Federal Register

Monday,
December 20, 2010

Part VIII

Department of Health and Human Services

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semi-annual issuance of an inventory of rulemaking actions under development throughout the Department with a view to offering summarized information about forthcoming regulatory actions for public review.

FOR FURTHER INFORMATION CONTACT: Dawn L. Smalls, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the Spring 2009 Agenda was published.

Please note that the rulemaking abstracts included in this paper issue of the **Federal Register** relate strictly to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities, as required by the Regulatory Flexibility Act of 1980. Also available in this issue of the **Register** is the Department's submission to the Fiscal Year 2011 Regulatory Plan, as required under Executive Order 12866.

The purpose of the Agenda is to encourage more effective public participation in the regulatory process, and HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda. The complete Regulatory Agenda of the Department is accessible online at www.reginfo.gov in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database.

Dated: September 21, 2010.

Dawn L. Smalls,

Executive Secretary,

Department of Health and Human Services.

Office of the Secretary—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
302	Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments **(Section 610 Review)**	0991–AB03

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
303	Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act **(Reg Plan Seq No. 41)**	0991–AB57

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Office of the Secretary—Completed Actions

Sequence Number	Title	Regulation Identifier Number
304	Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology **(Rulemaking Resulting From a Section 610 Review)**	0991–AB58

Substance Abuse and Mental Health Services Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
305	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10
306	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction **(Section 610 Review)**	0930–AA14

HHS

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
307	Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primate	0920–AA23

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
308	Control of Communicable Diseases: Foreign and Possessions	0920–AA12
309	Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus **(Section 610 Review)**	0920–AA32

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
310	Quality Assurance Requirements for Respirators	0920–AA04

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
311	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
312	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics **(Reg Plan Seq No. 45)**	0910–AC52
313	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
314	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
315	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
316	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
317	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
318	Import Tolerances for Residues of Unapproved New Animal Drugs in Food	0910–AF78
319	Laser Products; Amendment to Performance Standard	0910–AF87
320	Pet Food Labeling Requirements	0910–AG09
321	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10
322	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
323	Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910–AG18
324	Unique Device Identification **(Reg Plan Seq No. 46)**	0910–AG31
325	Cigars Subject to the Family Smoking Prevention and Tobacco Control Act	0910–AG38
326	Cigarette Warning Label Statements **(Reg Plan Seq No. 47)**	0910–AG41
327	General Hospital and Personal Use Devices: Designation of Special Controls for Infusion Pumps	0910–AG54
328	Food Labeling: Nutrition Labeling for Food Sold in Vending Machines **(Reg Plan Seq No. 48)**	0910–AG56
329	Food Labeling: Nutrition Labeling of Standard Menu Items in Chain Restaurants **(Reg Plan Seq No. 49)**	0910–AG57

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

HHS

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
330	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
331	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
332	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
333	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors **(Reg Plan Seq No. 50)**	0910–AF27
334	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
335	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
336	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
337	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
338	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
339	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
340	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88
341	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
342	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
343	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
344	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
345	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
346	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
347	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
348	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
349	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
350	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
351	Over-the-Counter (OTC) Drug Review—Antidiarrheal Drug Products	0910–AF63
352	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
353	Over-the-Counter (OTC) Drug Review—Certain Category II Active Ingredients	0910–AF95
354	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14
355	Produce Safety Regulation	0910–AG35
356	Modernization of the Current Food Good Manufacturing Practices Regulation	0910–AG36

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
357	Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation **(Completion of a Section 610 Review)**	0910–AG25
358	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	0910–AG33
359	Over-the-Counter Human Drugs; Labeling Requirements **(Completion of a Section 610 Review)**	0910–AG34

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
360	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81

HHS

Centers for Medicare & Medicaid Services—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
361	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-F) **(Section 610 Review)**	0938–AP32
362	Influenza Vaccination Standard for Certain Medicare Participating Providers and Suppliers(CMS-3213-P)	0938–AP92
363	Hospital Conditions of Participation: Requirements for Hospital Inpatient Psychiatric and Rehabilitation Units Excluded From the Prospective Payment System and LTCH Requirements (CMS-3177-P)	0938–AP97
364	Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2012 Rates and to the Long-Term Care Hospital PPS and RY 2012 Rates (CMS-1518-P) **(Reg Plan Seq No. 55)**	0938–AQ24
365	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2012 (CMS-1525-P) **(Reg Plan Seq No. 57)**	0938–AQ26
366	Changes to the ESRD Prospective Payment System for CY 2012 (CMS-1577-P)	0938–AQ27
367	Federal Funding for Medicaid Eligibility Determination and Enrollment Activities (CMS-2346-P)	0938–AQ53

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register**.

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
368	Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS-1503-C)	0938–AP79
369	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-C)	0938–AP82

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
370	Revisions to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2011 (CMS-4085-F)	0938–AP77
371	Electronic Health Record (EHR) Incentive Program (CMS-0033-F)	0938–AP78
372	Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System	0938–AP80
373	Hospital IPPS for Acute Care Hospitals and Fiscal Year 2010 Rates and to the Long-Term Care Hospital PPS and Rate Year 2010 Rates (CMS-1406-N)	0938–AQ03

Department of Health and Human Services (HHS)
Office of the Secretary (OS)

Proposed Rule Stage

302. REVISIONS TO REGULATIONS ADDRESSING THE OIG'S AUTHORITY TO IMPOSE CIVIL MONEY PENALTIES AND ASSESSMENTS (SECTION 610 REVIEW)

Legal Authority: 42 USC 1320a–7a; 42 USC 1395mm; 42 USC 1395w–27; 42 USC 1396b; PL 99–660; PL 107–188

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e mail communications.

Timetable:

Action	Date	FR Cite
NPRM	04/00/11	
NPRM Comment Period End	06/00/11	

Regulatory Flexibility Analysis Required: No

Agency Contact: Patrice S. Drew, Department of Health and Human Services, Office of the Secretary, Office of the Inspector General, 330 Independence Avenue SW., Washington, DC 20201
Phone: 202 619–1368
Email: patrice.drew@hhs.gov

RIN: 0991–AB03

Department of Health and Human Services (HHS)
Office of the Secretary (OS)

Final Rule Stage

303. MODIFICATIONS TO THE HIPAA PRIVACY, SECURITY, AND ENFORCEMENT RULES UNDER THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT

Regulatory Plan: This entry is Seq. No. 41 in part II of this issue of the **Federal Register**.

RIN: 0991–AB57

Department of Health and Human Services (HHS)
Office of the Secretary (OS)

Completed Actions

304. HEALTH INFORMATION TECHNOLOGY: INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA FOR ELECTRONIC HEALTH RECORD TECHNOLOGY (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 USC 300jj–14

Abstract: The Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology, will issue an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act. The certification criteria adopted in this initial set establish the technical capabilities and related standards that certified electronic health record (EHR) technology will need to include in support of the Medicare and Medicaid EHR Incentive Programs.

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/13/10	75 FR 2014
Interim Final Rule Comment Period End	03/15/10	
Interim Final Rule Effective	02/12/10	
Final Action	07/28/10	75 FR 44590

Regulatory Flexibility Analysis Required: No

Agency Contact: Steven Posnack, Policy Analyst, Department of Health and Human Services, Office of the Secretary, Office of the National Coordinator for Health Information Technology, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 690–7151

RIN: 0991–AB58

Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA)

Long-Term Actions

305. REQUIREMENTS GOVERNING THE USE OF SECLUSION AND RESTRAINT IN CERTAIN NONMEDICAL COMMUNITY–BASED FACILITIES FOR CHILDREN AND YOUTH

Legal Authority: PL 106–310, 42 USC 290jj to 290jj–2

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paolo Del Vecchio, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Room 13–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443–2619

RIN: 0930–AA10

306. OPIOID DRUGS IN MAINTENANCE OR DETOXIFICATION TREATMENT OF OPIATE ADDICTION (SECTION 610 REVIEW)

Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd–2; 42 USC 300xx–23; 42 USC 300x–27(a); 42 USC 300y–11

Abstract: This rule will amend the Federal opioid treatment program regulations. It will modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Timetable:

Action	Date	FR Cite
NPRM	06/19/09	74 FR 29153
NPRM Comment Period End	08/18/09	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: No

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Suite

HHS—SAMHSA — Long-Term Actions

2–1063, One Choke Cherry Road, Rockville, MD 20857

Phone: 240 276–2716

RIN: 0930–AA14

Department of Health and Human Services (HHS) — Proposed Rule Stage
Centers for Disease Control and Prevention (CDC)

307. CONTROL OF COMMUNICABLE DISEASES: FOREIGN AND POSSESSIONS REGULATIONS; NONHUMAN PRIMATE

Legal Authority: 42 USC 264

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Timetable:

Action	Date	FR Cite
NPRM	01/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, MS E03, CLFT Building 16, Room 4324, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA23

Department of Health and Human Services (HHS) — Final Rule Stage
Centers for Disease Control and Prevention (CDC)

308. CONTROL OF COMMUNICABLE DISEASES: FOREIGN AND POSSESSIONS

Legal Authority: 42 USC 243; 42 USC 264 and 265; 42 USC 267 and 268; 42 USC 270 and 271

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to interstate matters. This rule (42 CFR Part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/20/06	
Final Action	12/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Stacy Howard, Department of Health and Human Services, Centers for Disease Control and Prevention, MS E03, CLFT Building 16, Room 4324, Atlanta, GA 30329
Phone: 404 498–1600
Email: showard@cdc.gov

RIN: 0920–AA12

309. POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS: CHAPARE VIRUS (SECTION 610 REVIEW)

Legal Authority: PL 107–188

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: (1) The effect on human health as a result of exposure to the agent or toxin, (2) the degree of contagiousness of the agent or toxin, (3) the methods by which the agent or toxin is transferred to humans, (4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent and illness resulting from infection by the agent or toxin, and (5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After

HHS—CDC **Final Rule Stage**

consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Timetable:

Action	Date	FR Cite
NPRM	08/19/09	74 FR 159
NPRM Comment Period End	10/19/09	
Final Action	11/00/11	

Regulatory Flexibility Analysis Required: No

Agency Contact: Robbin Weyant, Department of Health and Human Services, Centers for Disease Control and Prevention, CLFT Building 20, Room 4202, 1600 Clifton Road NE., Atlanta, GA 30333
Phone: 404 718–2000

RIN: 0920–AA32

Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)

Long-Term Actions

310. QUALITY ASSURANCE REQUIREMENTS FOR RESPIRATORS

Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842(h); 30 USC 844

Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: (1) Upgrade of quality assurance requirements; (2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; and (3) revised approval label requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/10/08	73 FR 75045
NPRM Comment Period End	02/09/09	
NPRM Comment Period Reopened	03/04/09	74 FR 9381
NPRM Comment Period Reopened End	04/10/09	
NPRM Comment Period Reopening Extended	05/21/09	74 FR 23815
NPRM Comment Period End	10/09/09	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William E. Newcomb, Physical Scientist, Department of Health and Human Services, Centers for Disease Control and Prevention, 626 Cochran Mill Road, PO Box 18070, Pittsburgh, PA 15236
Phone: 412 386–5200

RIN: 0920–AA04

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Prerule Stage

311. FOOD LABELING: SAFE HANDLING STATEMENTS, LABELING OF SHELL EGGS; REFRIGERATION OF SHELL EGGS HELD FOR RETAIL DISTRIBUTION (SECTION 610 REVIEW)

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42 USC 243; 42 USC 264; 42 USC 271

Abstract: Section 101.17(h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) (21 CFR 16.5(a)(4)) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement, provided the words ''keep refrigerated'' appear on the principal display panel or information panel. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

HHS—FDA **Prerule Stage**

Timetable:

Action	Date	FR Cite
Begin Review	12/15/09	
End Review	12/00/10	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1802
Fax: 301 436–2636
Email: geraldine.june@fda.hhs.gov

RIN: 0910–AG06

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) — Proposed Rule Stage

312. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Regulatory Plan: This entry is Seq. No. 45 in part II of this issue of the **Federal Register**.

RIN: 0910–AC52

313. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antihistamine labeling claims for the common cold.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/00	65 FR 51780
NPRM (Amendment) (Common Cold)	10/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF31

314. OVER–THE–COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses acetaminophen safety. The third action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The fourth action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The last document finalizes the internal analgesic products monograph.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
Final Action (Required Warnings and Other Labeling)	04/29/09	74 FR 19385
Final Action (Correction)	06/30/09	74 FR 31177
Final Action (Technical Amendment)	11/25/09	74 FR 61512
NPRM (Acetaminophen)	03/00/11	
NPRM (Amendment) (Pediatric)	To Be	Determined
NPRM (Amendment) (Sodium Bicarbonate)	To Be	Determined
NPRM (Overindulgence/ Hangover)	To Be	Determined
Final Action (Internal Analgesics)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF36

315. OVER–THE–COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other professional labeling requirements for laxative drug products. The final action will address laxative drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
NPRM (Professional Labeling—Sodium Phosphate)	12/00/10	
NPRM (Professional Labeling)	To Be	Determined
Final Action (Laxative Drug Products)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF38

316. OVER–THE–COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses active ingredients reviewed under Time and Extent Applications. The second action addresses other safety and effectiveness issues for OTC sunscreen drug products. The third action finalizes sunscreen labeling and testing requirements for both ultraviolet B and ultraviolet A radiation protection. The fourth action addresses the safety of sunscreen products. The last action addresses combination products containing sunscreen and insect repellent ingredients.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM Comment Period End	12/26/07	
NPRM (Safety and Effectiveness)	12/00/10	
Final Action (UVA/UVB)	12/00/10	
NPRM (Time and Extent Applications)	04/00/11	
ANPRM (Safety)	04/00/11	
NPRM (Sunscreen and Insect Repellent)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF43

317. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses food handler products. The second action addresses testing requirements for healthcare professional products. The third action addresses the safety and effectiveness of consumer products. The final actions listed will address the healthcare, consumer, food handlers, and first aid antiseptic drug products respectively.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare)	06/17/94	59 FR 31402
NPRM (Consumer)	03/00/11	
NPRM (Food Handlers)	To Be	Determined
NPRM (Testing — Healthcare Professional Products)	To Be	Determined
Final Action (Healthcare)	To Be	Determined
Final Action (Consumer)	To Be	Determined
Final Action (Food Handlers)	To Be	Determined
Final Action (First Aid Antiseptic)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF69

318. IMPORT TOLERANCES FOR RESIDUES OF UNAPPROVED NEW ANIMAL DRUGS IN FOOD

Legal Authority: 21 USC 360b(a)(6); 21 USC 371

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for unapproved new animal drugs where edible portions of animals imported into the United States may contain residues of such drugs (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has established an import tolerance for that new animal drug and the residue of the new animal drug in the animal-derived food does not exceed that tolerance.

Timetable:

Action	Date	FR Cite
NPRM	03/00/11	
NPRM Comment Period End	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Thomas Moskal, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 101, (MPN–4, HFV–232), 7519 Standish Place, Rockville, MD 20855
Phone: 240 276–9242
Fax: 240 276–9241
Email: thomas.moskal@fda.hhs.gov

RIN: 0910–AF78

319. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

Legal Authority: 21 USC 360hh to 360ss; 21 USC 371; 21 USC 393

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard to achieve greater harmonization and reflect current science. In addition, the proposal would include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66 Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–6248
Fax: 301 847–8145
Email: nancy.pirt@fda.hhs.gov

RIN: 0910–AF87

320. PET FOOD LABELING REQUIREMENTS

Legal Authority: 21 USC 343; 21 USC 371; PL 110–85, sec 1002(a)(3)

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110-85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a) of the new law directs FDA to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite
NPRM	03/00/11	
NPRM Comment Period End	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 2642 (MPN–4, HFV–228), 7519 Standish Place, Rockville, MD 20855
Phone: 240 453–6865
Email: william.burkholder@fda.hhs.gov

RIN: 0910–AG09

321. PROCESS CONTROLS FOR ANIMAL FEED INGREDIENTS AND MIXED ANIMAL FEED

Legal Authority: 21 USC 342; 21 USC 350e; 21 USC 371; 21 USC 374; 42 USC 264; PL 110–85, sec 1002(a)(2)

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed, including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Timetable:

Action	Date	FR Cite
NPRM	03/00/11	
NPRM Comment Period End	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Kim Young, Deputy Director, Division of Compliance, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, Room 106 (MPN–4, HFV–230), 7519 Standish Place, Rockville, MD 20855
Phone: 240 276–9207
Email: kim.young@fda.hhs.gov

RIN: 0910–AG10

322. OVER–THE–COUNTER (OTC) DRUG REVIEW—PEDIATRIC DOSING FOR COUGH/COLD PRODUCTS

Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903

New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AG12

323. ELECTRONIC DISTRIBUTION OF CONTENT OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: This rule would require electronic package inserts for human drug and biological prescription products, in lieu of paper, which is currently used. These inserts contain prescribing information intended for healthcare practitioners. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Connie T. Jung, Senior Advisor for Pharmacy Affairs, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO32, Room 4254, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–4830
Email: connie.jung@fda.hhs.gov

RIN: 0910–AG18

324. UNIQUE DEVICE IDENTIFICATION

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the **Federal Register**.

RIN: 0910–AG31

325. CIGARS SUBJECT TO THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111–31, The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. Section 901 of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the Tobacco Control Act. This proposed rule would deem cigars to be subject to the Tobacco Control Act and include provisions to address public health concerns raised by cigars.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: May Nelson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, MD 20850
Phone: 877 287–1373
Fax: 240 276–3904
Email: may.nelson@fda.hhs.gov

RIN: 0910–AG38

326. CIGARETTE WARNING LABEL STATEMENTS

Regulatory Plan: This entry is Seq. No. 47 in part II of this issue of the **Federal Register**.

RIN: 0910–AG41

327. ● GENERAL HOSPITAL AND PERSONAL USE DEVICES: DESIGNATION OF SPECIAL CONTROLS FOR INFUSION PUMPS

Legal Authority: 21 USC 351 371; 21 USC 360 and 360c; 21 USC 360e and 360j; 21 USC 371

Abstract: Since 2003, FDA has seen a dramatic increase in the number of device recalls, as well as an increase in the number of death and serious injury reports submitted regarding infusion pumps. An analysis of the reports reveals that a majority of the recalls and failures were caused by user error and/or device design flaw. As a result of these incidents, FDA is proposing to designate a special controls guidance document as the special controls for infusion pumps. The agency believes that establishing these special controls for infusion pumps is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

Timetable:

Action	Date	FR Cite
NPRM	09/00/11	
NPRM Comment Period End	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Nancy Pirt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66 Room 4438, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–6248
Fax: 301 847–8145
Email: nancy.pirt@fda.hhs.gov

RIN: 0910–AG54

328. ● FOOD LABELING: NUTRITION LABELING FOR FOOD SOLD IN VENDING MACHINES

Regulatory Plan: This entry is Seq. No. 48 in part II of this issue of the **Federal Register**.

RIN: 0910–AG56

329. ● FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN CHAIN RESTAURANTS

Regulatory Plan: This entry is Seq. No. 49 in part II of this issue of the **Federal Register**.

RIN: 0910–AG57

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Final Rule Stage

330. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381

Abstract: The final rule would amend the postmarketing expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Final Action	08/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6362, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
Phone: 301 796–3469
Fax: 301 847–8440
Email: jane.baluss@fda.hhs.gov

RIN: 0910–AA97

331. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future. FDA has described a number of proposals in the proposed rule including requiring that gas use outlet connections on portable cryogenic medical gas containers be permanently attached to the valve body.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	10/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Patrick Raulerson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6368, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
Phone: 301 796–3522
Fax: 301 847–8440
Email: patrick.raulerson@fda.hhs.gov

RIN: 0910–AC53

332. CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS; REQUIREMENTS FOR PREGNANCY AND LACTATION LABELING

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR parts 201.56, 201.57, and 201.80). Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug in pregnancy. One of the deficiencies of the category system is that drugs may be assigned to the same category when the severity, incidence, and types of risk are quite different. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. Therefore, the revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation.

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End	08/27/08	
Final Action	10/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Rachel S. Bressler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation Research, WO 51, Room 6224, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
Phone: 301 796–4288

Fax: 301 847–8440
Email: rachel.bressler@fda.hhs.gov

RIN: 0910–AF11

333. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Regulatory Plan: This entry is Seq. No. 50 in part II of this issue of the **Federal Register**.

RIN: 0910–AF27

334. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment—Ephedrine Single Ingredient)	07/13/05	70 FR 40237
NPRM Comment Period End	11/10/05	
Final Action (Technical Amendment)	11/30/07	72 FR 67639
Final Action (Amendment—Single Ingredient Labeling)	01/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF32

335. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/05	70 FR 40232
NPRM Comment Period End	11/10/05	
Final Action (Technical Amendment)	03/19/07	72 FR 12730
Final Action	10/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF33

336. OVER–THE–COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Timetable:

Action	Date	FR Cite
Final Action (GRASE dosage forms)	10/00/11	
NPRM (Amendment)	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF35

337. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash. The second action addresses skin protectant products used to treat fever blisters and cold sores.

Timetable:

Action	Date	FR Cite
Final Action (Aluminum Acetate) (Technical Amendment)	03/06/09	74 FR 9759
Final Action (Technical Amendments)	02/01/08	73 FR 6014
Final Action (Diaper Rash)	10/00/11	
Final Action (Fever Blisters/Cold Sores)	10/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug

Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF42

338. USE OF MATERIALS DERIVED FROM CATTLE IN HUMAN FOOD AND COSMETICS

Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE.

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/14/04	69 FR 42256
Interim Final Rule Effective	07/14/04	
Interim Final Rule Comment Period End	10/12/04	
Interim Final Rule (Amendments)	09/07/05	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/05	
Interim Final Rule (Amendments) Comment Period End	11/07/05	
Interim Final Rule (Amendments)	04/17/08	73 FR 20785
Interim Final Rule (Amendments) Comment Period End	07/16/08	
Interim Final Rule (Amendments) Effective	07/16/08	
Final Action	04/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Amber McCoig, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–316), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2131
Fax: 301 436–2644
Email: amber.mccoig@fda.hhs.gov

RIN: 0910–AF47

339. LABEL REQUIREMENT FOR FOOD THAT HAS BEEN REFUSED ADMISSION INTO THE UNITED STATES

Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, ''UNITED STATES: REFUSED ENTRY.'' The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Timetable:

Action	Date	FR Cite
NPRM	09/18/08	73 FR 54106
NPRM Comment Period End	12/02/08	
Final Action	03/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Daniel Sigelman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, WO Building 1, Room 4245, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–4706
Email: daniel.sigelman@fda.hhs.gov

RIN: 0910–AF61

Department of Health and Human Services (HHS) Food and Drug Administration (FDA) — Long-Term Actions

340. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. FDA also published an Interim Final Rule in the same Federal Register (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review

by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Timetable:

Action	Date	FR Cite
ANPRM	02/06/97	62 FR 5700
ANPRM Comment Period End	06/06/97	
NPRM	03/13/03	68 FR 12157
NPRM Comment Period End	08/11/03	
Final Rule	06/25/07	72 FR 34752
Interim Final Rule	06/25/07	72 FR 34959
Interim Final Rule Comment Period End	10/24/07	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Linda Kahl, Senior Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–024), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–2784
Fax: 301 436–2657
Email: linda.kahl@fda.hhs.gov

RIN: 0910–AB88

341. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient phenylpropanolamine.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM Comment Period End	11/01/04	
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM Comment Period End	01/31/05	
NPRM (Phenyl-propanolamine)	12/22/05	70 FR 75988
NPRM Comment Period End	03/22/06	
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate)	08/01/06	71 FR 83358
Final Action (Phenyl-propanolamine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF34

342. OVER–THE–COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/06	71 FR 74474
NPRM Comment Period End	04/11/07	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF37

343. OVER–THE–COUNTER (OTC) DRUG REVIEW—OPHTHALMIC PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes the monograph for emergency first aid eyewash drug products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/03	68 FR 7917
Final Action (Amendment) (Emergency First Aid Eyewashes)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF39

344. OVER–THE–COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a

Abstract: The OTC drug review establishes conditions under which

OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM and final action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Timetable:

Action	Date	FR Cite
ANPRM (Plaque Gingivitis)	05/29/03	68 FR 32232
ANPRM Comment Period End	08/27/03	
NPRM (Plaque Gingivitis)	To Be	Determined
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF40

345. OVER–THE–COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The proposed rule addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/19/07	72 FR 71769
NPRM (Vaginal Contraceptive Drug Products)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF44

346. OVER–THE–COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM addresses the use of benzocaine for weight control. The first final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final action will finalize the proposed rule for weight control products containing benzocaine.

Timetable:

Action	Date	FR Cite
NPRM (Phenyl-propanolamine)	12/22/05	70 FR 75988
NPRM Comment Period End	03/22/06	
NPRM (Benzocaine)	To Be	Determined
Final Action (Phenyl-propanolamine)	To Be	Determined
Final Action (Benzocaine)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF45

347. OVER–THE–COUNTER (OTC) DRUG REVIEW—OVERINDULGENCE IN FOOD AND DRINK PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	01/05/05	70 FR 741
NPRM Comment Period End	04/05/05	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF51

348. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium

bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Timetable:

Action	Date	FR Cite
Final Action (Sodium Bicarbonate Labeling)	To Be	Determined
Final Action (Overindulgence Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF52

349. OVER–THE–COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching drug products containing hydroquinone.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51146
NPRM Comment Period End	12/27/06	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF53

350. OVER–THE–COUNTER (OTC) DRUG REVIEW—STIMULANT DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF56

351. OVER–THE–COUNTER (OTC) DRUG REVIEW—ANTIDIARRHEAL DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions address new labeling for antidiarrheal drug products.

Timetable:

Action	Date	FR Cite
NPRM (New Labeling)	To Be	Determined
Final Action (New Labeling)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF63

352. OVER–THE–COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AF70

353. OVER–THE–COUNTER (OTC) DRUG REVIEW—CERTAIN CATEGORY II ACTIVE INGREDIENTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA issued this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This rule will finalize the 2008 proposed rule.

Timetable:

Action	Date	FR Cite
NPRM	06/19/08	73 FR 34895
NPRM Comment Period End	09/17/08	
Final Action	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Matthew R. Holman, Ph.D., Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: matthew.holman@fda.hhs.gov

RIN: 0910–AF95

354. PRESCRIPTION DRUG MARKETING ACT OF 1987; PRESCRIPTION DRUG AMENDMENTS OF 1992; POLICIES, REQUIREMENTS, AND ADMINISTRATIVE PROCEDURES (SECTION 610 REVIEW)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Abstract: Pursuant to section 610 of the Regulatory Flexibility Act, FDA is currently undertaking a review of regulations promulgated under the Prescription Drug Marketing Act (PDMA) including those contained in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763). The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA solicited comments on the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

FDA received one comment on this review; and FDA notes that portions of the PDMA have been stayed in connection with *RxUSA Wholesale, Inc., v. HHS*, 467 F. Supp.2d 285 (E.D.N.Y. 2006), aff'd, 2008 U.S. App. LEXIS 14661 (2d Cir. 2008)); and that the litigation itself has been administratively closed (with either party having the right to reopen) through June 30, 2011. FDA is certifying that it is not feasible for the agency to complete its review by December 4, 2010, and therefore is extending the completion date by one year.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	12/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Howard Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301 847–8440
Email: pdma610(c)review@fda.hhs.gov

RIN: 0910–AG14

355. PRODUCE SAFETY REGULATION

Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264

Abstract: The Food and Drug Administration (FDA) has determined that enforceable standards (as opposed to voluntary recommendations) for the production and packing of fresh produce are necessary to ensure best practices are commonly adopted. FDA is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (GAPs Guide). The proposed rule also will reflect comments received on the agency's 1998 update of its GAPs guide and its July 2009 draft commodity specific guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be based on recommendations that are included in the GAPs guide, FDA does not intend to make the entire guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of modern preventive controls. The proposed rule also would emphasize the importance of environmental assessments to identify hazards and possible pathways of contamination and provide examples of risk reduction practices recognizing that operators must tailor their preventive controls to particular hazards and conditions affecting their operations. The requirements of the proposed rule would be scale appropriate and commensurate with the relative risks and complexity of individual operations. FDA intends to issue guidance after the proposed rule is finalized to assist industry in

complying with the requirements of the new regulation.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Samir Assar, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1636
Email: samir.assar@fda.hhs.gov

RIN: 0910–AG35

356. MODERNIZATION OF THE CURRENT FOOD GOOD MANUFACTURING PRACTICES REGULATION

Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264

Abstract: The Food and Drug Administration (FDA) is proposing to amend its current good manufacturing practices (CGMP) regulations (21 CFR part 110) for manufacturing, packing, or holding human food. This proposed rule would require food facilities to address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces. The proposed rule also would require food facilities to develop and implement preventive control systems. FDA is taking this action to better address changes that have occurred in the food industry and protect public health.

Timetable:

Action	Date	FR Cite
NPRM	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paul South, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–317), Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436–1640
Email: paul.south@fda.hhs.gov

RIN: 0910–AG36

Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

Completed Actions

357. STERILITY REQUIREMENT FOR AQUEOUS–BASED DRUG PRODUCTS FOR ORAL INHALATION (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360e; 21 USC 371; 21 USC 374; 21 USC 375

Abstract: FDA is undertaking a review of 21 CFR 200.51, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether this regulation on aqueous-based drug products for oral inhalation should be continued without change, or whether it should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for 21 CFR 200.51; (2) the nature of complaints or comments received concerning 21 CFR 200.51; (3) the complexity of 21 CFR 200.51; (4) the extent to which the regulation overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR 200.51. No comments were required. FDA's review of these regulations concluded that they should be continued without change.

Timetable:

Action	Date	FR Cite
Begin Review	05/01/09	
End Review	05/31/10	

Regulatory Flexibility Analysis Required: No

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6234, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
Phone: 301 796–3601
Fax: 301 847–8440
Email: howard.mullerjr@fda.hhs.gov

RIN: 0910–AG25

358. REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

Legal Authority: 21 USC 301 et seq, The Federal Food, Drug, and Cosmetic Act; PL 111–31, Family Smoking Prevention and Tobacco Control Act

Abstract: This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing section 102 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). FSPTCA sections 102 and 6(c)(1) require the Secretary to publish, within 270 days of enactment, a final rule regarding cigarettes and smokeless tobacco. This final rule must be identical, except for several changes identified in section 102(a)(2) of FSPTCA, to part 897 of the regulations promulgated by the Secretary of HHS in the August 28, 1996, issue of the Federal Register (61 FR 44396).

This final rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits, with limited exception, free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. The rule also prohibits the sale or

distribution of brand-identified promotional, non-tobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name.

FDA also published in the same issue of the Federal Register an advance notice of proposed rulemaking requesting comments, data, research, or other information on the regulation of outdoor advertising of cigarettes and smokeless tobacco.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/10	75 FR 13241
Final Rule	03/19/10	75 FR 13225
ANPRM Comment Period End	05/18/10	
Final Rule Effective	06/22/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Annette L. Marthaler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 9200 Corporate Boulevard, 100K, Rockville, MD 20850
Phone: 877 287–1373
Fax: 240 276–3904
Email: annette.marthaler@fda.hhs.gov

RIN: 0910–AG33

359. OVER–THE–COUNTER HUMAN DRUGS; LABELING REQUIREMENTS (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 5 USC 610

Abstract: Section 201.66 (21 CFR section 201.66) established a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as headings in bold type and the use of ''bullet points'' to introduce key information, and (3) minimum standards for type size and spacing. FDA issued the final rule to improve labeling after considering comments submitted to the agency following the publication of the proposed regulation in 1997. In 1999, FDA published the final rule and stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ''user-friendly'' visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product.

FDA undertook a review of section 201.66 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulation in section 201.66 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 201.66; (2) the nature of the complaints or comments received concerning the regulation in section 201.66; (3) the complexity of the regulations in section 201.66; (4) the extent to which the regulations in section 201.66 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling standard regulations in section 201.

No comments were received. FDA's review of these regulations concluded that they should be continued without change.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	08/03/09	
End Review of Current Regulation	05/27/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: M. Scott Furness, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO22, 10903 New Hamphsire Avenue, Silver Spring, MD 20993
Phone: 301 796–2090
Fax: 301 796–9899
Email: micheal.furness@fda.hhs.gov

RIN: 0910–AG34

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

360. HOME HEALTH AGENCY (HHA) CONDITIONS OF PARTICIPATION (COPS) (CMS–3819–P) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The CoPs were last revised in 1989. The new requirements will focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through federal programs while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	07/00/11	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards & Quality, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786–6617
Email: danielle.shearer@cms.hhs.gov

RIN: 0938–AG81

361. REQUIREMENTS FOR LONG–TERM CARE FACILITIES: HOSPICE SERVICES (CMS–3140–F) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This rule establishes that in order to participate in the Medicare and Medicaid programs, long-term care facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility. The rule also contains quality of care requirements.

Timetable:

Action	Date	FR Cite
NPRM	10/22/10	75 FR 65282
NPRM Comment Period End	12/21/10	
Final Action	10/00/13	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Patricia Brooks, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Mailstop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4561
Email: patricia.brooks@cms.hhs.gov

RIN: 0938–AP32

362. INFLUENZA VACCINATION STANDARD FOR CERTAIN MEDICARE PARTICIPATING PROVIDERS AND SUPPLIERS(CMS–3213–P)

Legal Authority: Social Security Act sec 1881, 1861, 1920, 1102, 1871, 1965

Abstract: This proposed rule would require certain Medicare providers and suppliers to offer all patients an annual influenza vaccination, unless medically inadvisable or if the patient declines vaccination. This proposed rule is intended to increase the number of patients receiving annual vaccination against seasonal influenza and to decrease the morbidity and mortality rate from influenza.

Timetable:

Action	Date	FR Cite
NPRM	01/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Lauren Oviatt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4683
Email: lauren.oviatt@cms.hhs.gov

RIN: 0938–AP92

363. HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HOSPITAL INPATIENT PSYCHIATRIC AND REHABILITATION UNITS EXCLUDED FROM THE PROSPECTIVE PAYMENT SYSTEM AND LTCH REQUIREMENTS (CMS–3177–P)

Legal Authority: 42 USC 1385 X; 42 USC 1396 d; 42 USC 1395 hh

Abstract: This proposed rule would transfer the existing process requirements for hospital inpatient psychiatric and rehabilitation units that are excluded from prospective payment systems to the hospital conditions of participation (CoPs) part of the Act. This would allow accrediting organizations to deem these units as part of their hospital accreditation process providing a timely and cost effective survey and certification process under the CoPs. In addition, this rule would propose long term care hospital requirements mandated by the Medicare, Medicaid and SCHIP Extension Act of 2007.

Timetable:

Action	Date	FR Cite
NPRM	05/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Capt. Katherine Berkhousen, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop S3–02–01, Baltimore, MD 21244
Phone: 410 786–1154
Email: katherine.berkhousen@cms.hhs.gov

RIN: 0938–AP97

364. ● PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND FY 2012 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND RY 2012 RATES (CMS–1518–P)

Regulatory Plan: This entry is Seq. No. 55 in part II of this issue of the **Federal Register**.

RIN: 0938–AQ24

365. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2012 (CMS–1525–P)

Regulatory Plan: This entry is Seq. No. 57 in part II of this issue of the **Federal Register**.

RIN: 0938–AQ26

366. ● CHANGES TO THE ESRD PROSPECTIVE PAYMENT SYSTEM FOR CY 2012 (CMS–1577–P)

Legal Authority: Sec 1881 of the Social Security Act

Abstract: This proposed rule would update the bundled payment system for End Stage Renal Disease (ESRD) facilities as required by the Medicare Improvments for Patients and Providers Act (MIPPA). These changes would be applicable to services furnished on or after January 1 annually.

Timetable:

Action	Date	FR Cite
NPRM	06/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janet Samen, Director, Division of Chronic Care Management, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4533
Email: janet.samen@cms.hhs.gov

RIN: 0938–AQ27

367. ● FEDERAL FUNDING FOR MEDICAID ELIGIBILITY DETERMINATION AND ENROLLMENT ACTIVITIES (CMS–2346–P)

Legal Authority: PL 111–148, sec 1413

HHS—CMS **Proposed Rule Stage**

Abstract: The Affordable Care Act requires States' residents to apply, enroll, receive determinations, and participate in the State health subsidy programs known as ''the Exchange''. The ACA requires many changes to State eligibility and enrollment systems and each State is responsible for developing a secure, electronic interface allowing the exchange of data. Existing legacy eligibility systems are not able to implement the numerous requirements. This proposed rule is key to informing States about the higher rates that CMS will provide to help them update or build legacy eligibility systems that meet the ACA requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/08/10	75 FR 68583
NPRM Comment Period End	01/07/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Richard H. Friedman, Director, Division of State Systems, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop S3–18–13, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4451
Email: richard.friedman@cms.hhs.gov

RIN: 0938–AQ53

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

368. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND PART B FOR CY 2011 (CMS–1503–C)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Abstract: This annual final rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B for CY 2011.

Timetable:

Action	Date	FR Cite
NPRM	07/13/10	75 FR 40040
NPRM Comment Period End	09/24/10	
Final Action	12/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Bazell, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6960
Email: carol.bazell@cms.hhs gov

RIN: 0938–AP79

369. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2011 (CMS–1504–C)

Legal Authority: sec 1833 of the Social Security Act; BBA, BA, BIPA, MMA, PPACA

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the Ambulatory Surgical Center Payment System list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	08/03/10	75 FR 46169
NPRM Comment Period End	08/31/10	
Final Action	12/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alberta Dwivedi, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–01–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–0763
Email: alberta.dwivedi@cms.hhs.gov

RIN: 0938–AP82

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)

Completed Actions

370. REVISIONS TO THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS FOR CONTRACT YEAR 2011 (CMS–4085–F)

Legal Authority: MMA 2003; MIPPA (title XVIII of the Social Security Act)

Abstract: This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment; implement new policy such as a Part D formulary policy; and clarify program policy.

Timetable:

Action	Date	FR Cite
NPRM	10/22/09	74 FR 54634
NPRM Comment Period End	12/07/09	
Final Action	04/15/10	75 FR 19678

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Alissa Deboy, Director, Division of Drug Plan Policy and Quality, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop

C1–26–26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–6041
Email: alissa.deboy@cms.hhs.gov

RIN: 0938–AP77

371. ELECTRONIC HEALTH RECORD (EHR) INCENTIVE PROGRAM (CMS–0033–F)

Legal Authority: PL 111–5 (The American Recovery and Reinvestment Act of 2009, Title IV of Division B, Medicare and Medicaid Health Information Technology)

Abstract: This rule would implement provisions of the American Recovery Act of 2009 (Recovery Act) that authorize incentive payments to eligible professionals (EPS) and eligible hospitals participating in the Medicare and Medicaid programs for adopting and becoming meaningful users of certified electronic health records (HER) technology. In accordance with the Recovery Act, the rule will establish maximum annual incentive amounts and include Medicare penalties for failing to meaningfully use EHRs beginning in 2015.

Timetable:

Action	Date	FR Cite
NPRM	01/13/10	75 FR 1843
NPRM Comment Period End	03/15/10	
Final Action	07/28/10	75 FR 44413

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Elizabeth S. Holland, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2–26–17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–1309
Email: elizabeth.holland@cms.hhs.gov

RIN: 0938–AP78

372. PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM

Legal Authority: Sec 1886(d) of the Social Security Act

Abstract: This rule updates the fiscal year (FY) 2011 hospital inpatient prospective payment systems (IPPS) and long-term care prospective payment system (LTCH PPS). This rule payments to hospitals for inpatient services that are contained in the Patient Protection and Affordable Care Act (the Affordable Care Act) as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA) (collectively known as the Affordable Care Act). It would also specify statutorily required changes to the amounts and factors used to determine the rates for Medicare acute care hospital inpatient services for operating costs and capital-related costs, and for long-term care hospital costs.

Timetable:

Action	Date	FR Cite
NPRM	05/04/10	75 FR 23851
NPRM Comment Period End	06/18/10	
Second NPRM	06/02/10	75 FR 30917
Second NPRM Comment Period End	07/02/10	
Final Action	08/16/10	75 FR 50041

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Tiffany Swygert, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4–25–11, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4642
Email: tiffany.swygert@cms.hhs.gov

RIN: 0938–AP80

373. ● HOSPITAL IPPS FOR ACUTE CARE HOSPITALS AND FISCAL YEAR 2010 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND RATE YEAR 2010 RATES (CMS–1406–N)

Legal Authority: PL 111 148; PL 111–152

Abstract: This notice contains the final wage indices, hospital reclassifications, payment rates, impacts, and other related tables effective for the fiscal year (FY) 2010 hospital inpatient prospective payment systems (IPPS) and rate year 2010 long-term care hospital (LTCH) prospective payment system (PPS) . The rates, tables, and impacts included in this notice reflect changes required or resulting from the implementation of several provisions of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010. These provisions require the extension of the expiration date for certain geographic reclassifications and special exception wage indices through September 30, 2010, and certain market basket updates for the IPPS and LTCH PPS effective April 1, 2010.

Timetable:

Action	Date	FR Cite
Final Action	06/02/10	75 FR 31118

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Tzvi Hefter, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786–4487
Email: tzvi.hefter@cms.hhs.gov

RIN: 0938–AQ03

[FR Doc. 2010–30444 Filed 12–17–10; 8:45 am]

BILLING CODE 4150–24–S