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Part VII

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 following Agenda presents the results of the statutorily required semi-annual inventory of rulemaking actions currently under development within the U.S. Department of Health and Human Services (HHS). We hope that this information will enable interested members of the public to more effectively participate in the Department's regulatory activity.

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 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 most recent Agenda was published on December 7, 2009. Please note that the actions included in this issue of the **Federal Register,** as required by the Regulatory Flexibility Act of 1980, relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities.

The purpose of the Agenda is to encourage more effective public participation in the regulatory process. HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda. The complete Agenda 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: March 10, 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
120	Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act	0991–AB57

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
121	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—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
122	Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addiction **(Section 610 Review)**	0930–AA14

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

Sequence Number	Title	Regulation Identifier Number
123	Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930–AA10

HHS

Centers for Disease Control and Prevention—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
124	Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920–AA14
125	Control of Communicable Diseases: Foreign Quarantine Regulations, Nonhuman Primate	0920–AA23
126	Total Inward Leakage Requirements for Respirators	0920–AA33

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
127	Quality Assurance Requirements for Respirators	0920–AA04
128	Control of Communicable Diseases: Foreign Quarantine	0920–AA12

Centers for Disease Control and Prevention—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
129	Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus **(Section 610 Review)**	0920–AA32

Centers for Disease Control and Prevention—Completed Actions

Sequence Number	Title	Regulation Identifier Number
130	Control of Communicable Diseases: Interstate Quarantine, Passenger Information	0920–AA27

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
131	Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution **(Section 610 Review)**	0910–AG06
132	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**	0910–AG14
133	Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation **(Section 610 Review)**	0910–AG25
134	Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents	0910–AG33
135	Over-the-Counter Human Drugs; Labeling Requirements **(Section 610 Review)**	0910–AG34

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
136	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910–AC52
137	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
138	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
139	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
140	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
141	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
142	Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910–AG10

HHS

Food and Drug Administration—Proposed Rule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
143	Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph	0910–AG12
144	Unique Device Identification	0910–AG31
145	Produce Safety Regulation	0910–AG35
146	Modernization of the Current Food Good Manufacturing Practices Regulation	0910–AG36
147	Cigars Subject to the Family Smoking Prevention and Tobacco Control Act	0910–AG38

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
148	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
149	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
150	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910–AF11
151	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors	0910–AF27
152	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910–AF32
153	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
154	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910–AF35
155	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910–AF42
156	Use of Materials Derived From Cattle in Human Food and Cosmetics	0910–AF47
157	Label Requirement for Food That Has Been Refused Admission Into the United States	0910–AF61

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
158	Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910–AB88
159	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910–AF34
160	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910–AF37
161	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910–AF39
162	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910–AF40
163	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910–AF44
164	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910–AF45
165	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910–AF51
166	Over-the-Counter (OTC) Drug Review—Antacid Products	0910–AF52
167	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910–AF53
168	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910–AF56
169	Over-the-Counter Antidiarrheal Drug Products	0910–AF63
170	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910–AF70
171	Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients	0910–AF95

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
172	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910–AC55
173	Over-the-Counter (OTC) Drug Review—Acne Drug Products Containing Benzoyl Peroxide	0910–AG00

HHS

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
174	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) **(Section 610 Review)**	0938–AG81
175	Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P) **(Section 610 Review)**	0938–AP32
176	Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long-Term Care Hospital PPS and RY 2011 Rates (CMS-1498-P)	0938–AP80
177	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-P)	0938–AP82
178	Home Health Prospective Payment System Refinements and Rate Update for CY 2011 (CMS-1510-P)	0938–AP88
179	Omnibus Influenza Immunization (CMS-3213-P)	0938–AP92
180	Proposed Changes to the Hospital Conditions of Participation: Requirements for Hospital Psychiatric and Rehabilitation Units Excluded From the Prospective Payment System (CMS-3177-P)	0938–AP97

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
181	Revisions to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2011 (CMS-4085-F)	0938–AP77

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
182	Electronic Claims Attachments Standards (CMS-0050-IFC)	0938–AK62
183	Revisions to Payment Policies Under the Physician Fee Schedule for CY 2010 (CMS-1413-FC)	0938–AP40
184	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-FC)	0938–AP41

Department of Health and Human Services (HHS)

Office of the Secretary (OS)

Proposed Rule Stage

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

Legal Authority: PL 111–5, secs 13400 to 13410

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to modify the HIPAA Privacy, Security, and Enforcement Rules as necessary to implement the privacy, security, and certain enforcement provisions of subtitle D of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Timetable:

Action	Date	FR Cite
NPRM	05/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Andra Wicks, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201
Phone: 202 205–2292
Fax: 202 205–4786
Email: andra.wicks@hhs.gov

RIN: 0991–AB57

Department of Health and Human Services (HHS) **Final Rule Stage**

Office of the Secretary (OS)

121. 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	05/00/10	
Final Action Effective	06/00/10	

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) **Final Rule Stage**

Substance Abuse and Mental Health Services Administration (SAMHSA)

122. 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	09/00/10	

Regulatory Flexibility Analysis Required: No

Agency Contact: Nicholas Reuter, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Suite 2–1063, One Choke Cherry Road, Rockville, MD 20857
Phone: 240 276–2716

RIN: 0930–AA14

Department of Health and Human Services (HHS) **Long-Term Actions**

Substance Abuse and Mental Health Services Administration (SAMHSA)

123. 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

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

Proposed Rule Stage

124. CONTROL OF COMMUNICABLE DISEASES: FOREIGN QUARANTINE REGULATIONS, PROPOSED REVISION OF HHS/CDC ANIMAL IMPORTATION REGULATIONS

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 designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. Currently the regulations restrict the importation of nonhuman primates, dogs, cats, small turtles, etiologic agents, hosts, and vectors, such as bats (42 CFR sections 71.53, 71.51, 71.52, 71.54). In addition, CDC has recently issued a series of emergency orders restricting the importation of African rodents (42 CFR section 71.56) and civets (67 FR 3364-01). CDC is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the United States (42 CFR parts 71, subpart F).

Timetable:

Action	Date	FR Cite
ANPRM	07/31/07	72 FR 41676
ANPRM Comment Period End	10/01/07	
Notice Extending ANPRM Comment Period	10/01/07	72 FR 55729
ANPRM Extended Comment Period End	12/01/07	
NPRM	11/00/10	

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–AA14

125. CONTROL OF COMMUNICABLE DISEASES: FOREIGN QUARANTINE 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 2 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	08/00/10	

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–AA23

126. TOTAL INWARD LEAKAGE REQUIREMENTS FOR RESPIRATORS

Legal Authority: 29 USC 651 et seq; 29 USC 657(g); 30 USC 3; 30 USC 7; 30 USC 811; 30 USC 842(h) and 844

Abstract: The Centers for Disease Control and Prevention (CDC) proposes to establish total inward leakage (TIL) requirements under 42 CFR part 84 for half-mask air-purifying particulate respirators approved by the National Institute for Occupational Safety and Health (NIOSH) of CDC.

Timetable:

Action	Date	FR Cite
NPRM	10/30/09	74 FR 66935
NPRM Comment Period End	12/29/09	
NPRM Comment Period Reopened	04/00/10	

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–AA33

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

Final Rule Stage

127. 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.

HHS—CDC **Final Rule Stage**

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	12/00/10	

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

128. CONTROL OF COMMUNICABLE DISEASES: FOREIGN QUARANTINE

Legal Authority: 42 USC 243; 42 USC 248 and 249

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. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with 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 rule will also modify current Federal regulations governing the apprehension, quarantine isolation, and conditional release of individuals suspected of carrying a quarantinable disease, while respecting individual autonomy. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause a pandemic.

Timetable:

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

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

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

Long-Term Actions

129. 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 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	To Be Determined	

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)

Completed Actions

130. CONTROL OF COMMUNICABLE DISEASES: INTERSTATE QUARANTINE, PASSENGER INFORMATION

Legal Authority: 25 USC 198.231; 25 USC 1661; 42 USC 243; 42 USC 248; 42 USC 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response.

Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of individuals who may have been exposed. This provision, which was proposed section 70.4, would require any airline operating in interstate traffic to solicit and electronically submit certain passenger information to CDC for use in contact tracing when necessary to protect the vital interests of an individual, or other persons, in regard to significant health risks.

Timetable:

Action	Date	FR Cite
NPRM	11/30/05	70 FR 71892
NPRM Comment Period End	01/30/06	
Merged With 0920–AA22	02/12/10	

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–AA27

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

Prerule Stage

131. 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. 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.

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

132. 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: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. 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 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 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).

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/08	
End Review of Current Regulation	06/00/10	

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
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RIN: 0910–AG14

133. STERILITY REQUIREMENT FOR AQUEOUS–BASED DRUG PRODUCTS FOR ORAL INHALATION (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.

Timetable:

Action	Date	FR Cite
Begin Review	05/01/09	
End Review	05/00/10	

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
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RIN: 0910–AG25

134. 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 will also publish 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
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RIN: 0910–AG33

HHS—FDA **Prerule Stage**

135. OVER–THE–COUNTER HUMAN DRUGS; LABELING REQUIREMENTS (SECTION 610 REVIEW)

Legal Authority: 5 USC 610

Abstract: Part 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 Helvetica type style 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 is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in part 201.66. The purpose of this review is to determine whether the regulation in part 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 part 201.66; (2) the nature of the complaints or comments received concerning the regulation in part 201.66; (3) the complexity of the regulations in part 201.66; (4) the extent to which the regulations in part 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 part 201.

The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	08/03/09	
End Review of Current Regulation	05/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AG34

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

Proposed Rule Stage

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

Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive.

Timetable:

Action	Date	FR Cite
NPRM	10/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Martha Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6352, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002
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RIN: 0910–AC52

137. 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)	03/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug

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RIN: 0910–AF31

138. 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	
NPRM (Over-indulgence/ Hangover)	To Be	Determined
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
Final Action (Internal Analgesics)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF36

139. 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)	10/00/10	
NPRM (Professional Labeling)	To Be	Determined
Final Action (Laxative Drug Products)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF38

140. 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 effectiveness issues for OTC sunscreen drug products. The third action finalizes sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection. 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 (Time and Extent Applications)	07/00/10	
NPRM (Effectiveness)	10/00/10	
Final Action (UVA/UVB)	10/00/10	
NPRM (Sunscreen and Insect Repellent)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human

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RIN: 0910–AF43

141. 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, and first aid antiseptic drug products respectively.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF69

142. 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
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RIN: 0910–AG10

143. PEDIATRIC DOSING FOR COUGH, COLD, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE; PROPOSED AMENDMENT OF FINAL MONOGRAPH

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	12/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AG12

144. UNIQUE DEVICE IDENTIFICATION

Legal Authority: Not Yet Determined

Abstract: The Food and Drug Administration Amendments Act of 2007, amended the Federal Food, Drug, and Cosmetic Act by adding section 519(f) (21 USC 360i(f)). This section requires FDA to promulgate regulations establishing a unique identification system for medical devices requiring the label of medical devices to bear a unique identifier, unless FDA specifies an alternative placement or provides for exceptions. The unique identifier must adequately identify the device through distribution and use, and may include information on the lot or serial number.

Timetable:

Action	Date	FR Cite
NPRM	12/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: John J. Crowley, Senior Advisor for Patient Safety, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 2315, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AG31

145. 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	12/00/10	

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
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RIN: 0910–AG35

146. 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	03/00/11	

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
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RIN: 0910–AG36

147. ● 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	06/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AG38

Department of Health and Human Services (HHS) **Final Rule Stage**

Food and Drug Administration (FDA)

148. 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	11/00/10	

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
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RIN: 0910–AA97

149. 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.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	03/00/11	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC53

150. 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	03/00/11	

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
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RIN: 0910–AF11

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

Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; . . .

Abstract: The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End	12/06/96	
NPRM Comment Period Reopened	04/28/03	68 FR 22341
NPRM Comment Period Extended	06/27/03	68 FR 38247
NPRM Comment Period End	08/26/03	
NPRM Comment Period Reopened	08/01/06	71 FR 43392
NPRM Comment Period End	09/15/06	
Final Action	10/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF27

152. 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)	09/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF32

153. 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	03/00/11	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF33

154. 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)	12/00/10	
NPRM (Amendment)	To Be Determined	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF35

155. 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 addresses skin protectant products used to treat fever blisters and cold sores. The second action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash.

Timetable:

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF42

156. 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	10/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF47

157. 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: John D. Reilly, Regulatory Counsel, Department of Health and Human Services, Food and

HHS—FDA **Final Rule Stage**

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RIN: 0910–AF61

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

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

Legal Authority: 21 USC 321; 21 USC 342 and 343; 21 USC 348; 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
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RIN: 0910–AB88

159. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF34

160. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF37

161. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF39

162. 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

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RIN: 0910–AF40

163. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF44

164. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF45

165. 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

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RIN: 0910–AF51

166. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF52

167. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF53

168. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF56

169. OVER–THE–COUNTER 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF63

170. 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF70

171. STATUS OF CERTAIN ADDITIONAL OVER–THE–COUNTER DRUG 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: Walter J. Ellenberg, Regulatory Project Management Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO–22, Room 5488, 10903 New Hampshire Avenue, Silver Spring, MD 20993
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RIN: 0910–AF95

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

Completed Actions

172. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES

Legal Authority: PL 105–115, sec 121

Abstract: Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The final rule adopts CGMPs that reflect the unique characteristics of PET drugs.

Timetable:

Action	Date	FR Cite
NPRM	09/20/05	70 FR 55038
NPRM Comment Period End	12/19/05	
Final Action	12/10/09	74 FR 65409

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AC55

173. OVER–THE–COUNTER (OTC) DRUG REVIEW—ACNE DRUG PRODUCTS CONTAINING BENZOYL PEROXIDE

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. This action will address acne drug products containing benzoyl peroxide.

Timetable:

Action	Date	FR Cite
Final Action	03/04/10	75 FR 9767

Regulatory Flexibility Analysis Required: Yes

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HHS—FDA **Completed Actions**

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RIN: 0910–AG00

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

Proposed Rule Stage

174. 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), last set in 1999, that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements 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	09/00/10	

Regulatory Flexibility Analysis Required: Undetermined

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RIN: 0938–AG81

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

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This proposed rule would establish that in order to participate in the Medicare and Medicaid programs, long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility. We are proposing new requirements to ensure that quality hospice care is provided to eligible residents.

Timetable:

Action	Date	FR Cite
NPRM	03/00/11	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP32

176. PROPOSED CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS FOR ACUTE CARE HOSPITALS AND FY 2011 RATES AND TO THE LONG–TERM CARE HOSPITAL PPS AND RY 2011 RATES (CMS–1498–P)

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

Abstract: This annual proposed rule would revise the Medicare hospital inpatient and long-term care prospective payment systems for operating and capital-related costs to implement changes arising from our continuing experience with these systems. These changes would be applicable to services furnished on or after October 1st.

Timetable:

Action	Date	FR Cite
NPRM	04/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP80

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

Legal Authority: sec 1833 of the Social Security Act

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also proposes changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1st.

Timetable:

Action	Date	FR Cite
NPRM	06/00/10	

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
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RIN: 0938–AP82

HHS—CMS **Proposed Rule Stage**

178. HOME HEALTH PROSPECTIVE PAYMENT SYSTEM REFINEMENTS AND RATE UPDATE FOR CY 2011 (CMS–1510–P)

Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895

Abstract: This annual proposed rule would update the 60-day national episode rate (based on the applicable Home Health Market Basket Update and case-mix adjustment) and would also update the national per-visit rates (used to calculate low utilization payment adjustments (LUPAs) and outlier payments) amounts under the Medicare Prospective Payment System for home health agencies. These changes would be applicable to services furnished on or after January 1st.

Timetable:

Action	Date	FR Cite
NPRM	07/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP88

179. ● OMNIBUS INFLUENZA IMMUNIZATION (CMS–3213–P)

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

Abstract: This proposed rule would require certain providers to offer all patients or residents an influenza immunization annually. The providers required to do so are hospitals, intermediate care facilities, critical access hospitals, rural health clinics, Federally qualified health centers, ESRD facilities, psychiatric residential treatment facilities, and inpatient rehabilitation facilities. This proposed rule is based on the most recent recommendations from the CDC's Advisory 3 Committee on Immunization Practices. The goal of this proposed rule is to improve influenza immunization rates for all patients and residents and to address the disparities in immunization rates

Timetable:

Action	Date	FR Cite
NPRM	09/00/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP92

180. ● PROPOSED CHANGES TO THE HOSPITAL CONDITIONS OF PARTICIPATION: REQUIREMENTS FOR HOSPITAL PSYCHIATRIC AND REHABILITATION UNITS EXCLUDED FROM THE PROSPECTIVE PAYMENT SYSTEM (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 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.

Timetable:

Action	Date	FR Cite
NPRM	01/00/11	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP97

Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) **Long-Term Actions**

181. 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	10/00/12	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP77

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

Completed Actions

182. ELECTRONIC CLAIMS ATTACHMENTS STANDARDS (CMS–0050–IFC)

Legal Authority: 42 USC 1320d–2(a)(2)(B)

Abstract: This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes.

Timetable:

Action	Date	FR Cite
NPRM	09/23/05	70 FR 55989
NPRM Comment Period End	11/22/05	
Withdrawn	01/25/10	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AK62

183. REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE FOR CY 2010 (CMS–1413–FC)

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

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

Timetable:

Action	Date	FR Cite
NPRM	07/13/09	74 FR 33520
NPRM Comment Period End	08/31/09	
Final Action	11/25/09	74 FR 61738

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP40

184. CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2010 (CMS–1414–FC)

Legal Authority: BBA; BBA; BIPA; MMA; MMSEA; MIPPA; DRA; TRHCA

Abstract: This annual rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, the rule describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also changes the Ambulatory Surgical Center Payment System list of services and rates. These changes are applicable to services furnished on or after January 1st.

Timetable:

Action	Date	FR Cite
NPRM	07/20/09	74 FR 35231
NPRM Comment Period End	08/31/09	
Final Action	11/20/09	74 FR 60315

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AP41

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