DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I–V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (E.O.) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Gramling, Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; (202) 690–5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential human services. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the regulatory activities that the Department expects to undertake in the foreseeable future to advance this mission. The purpose of the Agenda is to encourage more effective public participation in the regulatory process. The regulatory actions forecasted in this Agenda reflect the priorities of HHS Secretary Xavier Becerra and the Biden-Harris Administration. Accordingly, this Agenda contains rulemakings aimed at expanding access to health care, tackling disparities and advancing equity, increasing the nation's public health preparedness, and supporting the wellbeing of families and communities, among other policy priorities.

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at *http://www.RegInfo.gov.*

Elizabeth J. Gramling,

HHS Executive Secretary.

OFFICE OF THE SECRETARY—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
301	Limiting the Effect of Exclusions Implemented Under the Social Security Act **(Rulemaking Resulting From a Section 610 Review)**.	0991–AC11

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
302	Medications for the Treatment of Opioid Use Disorder **(Reg Plan Seq No. 56)**	0930–AA39

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

CENTERS FOR DISEASE CONTROL AND PREVENTION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
303	Control of Communicable Diseases; Foreign Quarantine **(Reg Plan Seq No. 57)**	0920–AA75

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

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
304	Medication Guide; Patient Medication Information	0910–AH68
305	Requirements for Tobacco Product Manufacturing Practice	0910–AH91
306	Administrative Detention of Tobacco Products	0910–AI05
307	Nutrient Content Claims, Definition of Term: Healthy	0910–AI13
308	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	0910–AI57
309	Amendments to the Final Rule Regarding the List of Bulk Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act **(Section 610 Review)**.	0910–AI70
310	Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act **(Section 610 Review)**.	0910–AI71

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
311	Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format.	0910–AG27
312	Sunlamp Products; Amendment to the Performance Standard	0910–AG30
313	Mammography Quality Standards Act **(Reg Plan Seq No. 63)**	0910–AH04
314	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910–AH14
315	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act.	0910–AH81
316	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910–AI15
317	Tobacco Product Standard for Characterizing Flavors in Cigars **(Reg Plan Seq No. 65)**	0910–AI28
318	Tobacco Product Standard for Menthol in Cigarettes **(Reg Plan Seq No. 67)**	0910–AI60

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

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
319	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910–AH11
320	Nicotine Toxicity Warnings	0910–AH24
321	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910–AH56
322	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products.	0910–AI61

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
323	Requirements For Additional Traceability Records For Certain Foods	0910–AI44

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
324	Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS–4198)	0938–AU59
325	Transitional Coverage for Emerging Technologies (CMS–3421) **(Reg Plan Seq No. 71)**	0938–AU86
326	CY 2024 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1784) **(Section 610 Review)**.	0938–AV07
327	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2024 Rates (CMS–1785) **(Section 610 Review)**.	0938–AV08
328	CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1786) **(Section 610 Review)**.	0938–AV09

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

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
329	Omnibus COVID–19 Health Care Staff Vaccination (CMS–3415) **(Section 610 Review)**	0938–AU75

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
330	CY 2023 Home Health Prospective Payment System Rate Update and Home Infusion Therapy Services Payment Update (CMS–1766) **(Completion of a Section 610 Review)**.	0938–AU77
331	CY 2023 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (CMS–1768) **(Completion of a Section 610 Review)**.	0938–AU79
332	FY 2023 Inpatient Psychiatric Facilities Prospective Payment System Rate (CMS–1769) **(Completion of a Section 610 Review)**.	0938–AU80
333	CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1770) **(Completion of a Section 610 Review)**.	0938–AU81

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS—Continued

Sequence No.	Title	Regulation Identifier No.
334	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (CMS–1771) **(Completion of a Section 610 Review)**.	0938–AU84

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Office of the Secretary (OS)

Proposed Rule Stage

301. Limiting the Effect of Exclusions Implemented Under the Social Security Act (Rulemaking Resulting From a Section 610 Review) [0991–AC11]

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: HHS proposes to remove the regulatory provisions at issue, in order to align the regulation with the intent of the Social Security Act and current practice. Exclusions implemented under the Social Security Act prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in federal healthcare programs. Instead of only being barred from participating in all federal healthcare programs, certain regulatory provisions have resulted in these type of exclusion actions being given an overly broad government-wide effect, and excluded parties have been barred from participating in all Federal procurement and non-procurement actions. However, because Social Security Act exclusions are not issued under an agency's suspension and debarment authority, they do not stop individuals from participating in all federal procurement and non-procurement actions. For an agency to bar individuals from participating in all procurement and non-procurement activities, it must exercise its suspension and debarment authority under the Federal Acquisition Regulation or the Nonprocurement Common Rule.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Tiffani Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue SW, Washington, DC 20201, *Phone:* 202 768–0628, *Email: tiffani.redding@hhs.gov.*

RIN: 0991–AC11

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Proposed Rule Stage

302. Medications for the Treatment of Opioid Use Disorder [0930–AA39]

Regulatory Plan: This entry is Seq. No. 56 in part II of this issue of the **Federal Register**.

RIN: 0930–AA39

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC)

Final Rule Stage

303. Control of Communicable Diseases; Foreign Quarantine [0920–AA75]

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

RIN: 0920–AA75

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

304. Medication Guide; Patient Medication Information [0910–AH68]

Legal Authority: 21 U.S.C. 321 *et seq.;* 42 U.S.C. 262; 42 U.S.C. 264; 21 U.S.C. 371

Abstract: The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution. The proposed rule would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Chris Wheeler, Supervisory Project Manager, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 3330, Silver Spring, MD 20993, *Phone:* 301 796–0151, *Email: chris.wheeler@fda.hhs.gov.*

RIN: 0910–AH68

305. Requirements for Tobacco Product Manufacturing Practice [0910–AH91]

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f

Abstract: The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. This proposal would help prevent the manufacture and distribution of contaminated and otherwise nonconforming tobacco products. This proposed rule provides manufacturers with flexibility in the manner in which they comply with the proposed requirements while giving FDA the ability to enforce regulatory requirements, thus helping to assure the protection of public health.

Timetable:

Action	Date	FR Cite
NPRM	12/00/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Matthew Brenner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–

1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH91

306. Administrative Detention of Tobacco Products [0910–AI05]

Legal Authority: 21 U.S.C. 334; 21 U.S.C. 371

Abstract: FDA is proposing a regulation to establish requirements for the administrative detention of tobacco products. This proposed rule, when finalized, would allow FDA to administratively detain tobacco products encountered during inspections of manufacturers or other establishments that manufacture, process, pack, or hold tobacco products that an authorized FDA representative conducting the inspection has reason to believe are adulterated or misbranded. The intent of administrative detention is to protect public health by preventing the distribution or use of tobacco products encountered during inspections that are believed to be adulterated or misbranded until FDA has had time to consider the appropriate action to take and, where appropriate, to initiate legal action.

Timetable:

Action	Date	FR Cite
NPRM	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Quynh Nguyen, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

Laura Chilaka, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AI05

307. Nutrient Content Claims, Definition of Term: Healthy [0910–AI13]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: The proposed rule would update the definition for the implied nutrient content claim ''healthy'' to be consistent with current nutrition science and federal dietary guidelines. The proposed rule would revise the requirements for when the claim ''healthy'' can be voluntarily used in the labeling of human food products to indicate that a food, because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations and helps consumers maintain healthy dietary practices.

Timetable:

Action	Date	FR Cite
NPRM	09/29/22	87 FR 59168
NPRM Comment Period End.	12/28/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Vincent De Jesus, Nutritionist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, (HFS–830), Room 3D–031, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1774, *Fax:* 301 436–1191, *Email: vincent.dejesus@fda.hhs.gov.*

RIN: 0910–AI13

308. Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies [0910–AI57]

Legal Authority: 21 U.S.C. 355; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262

Abstract: FDA is proposing to amend 21 CFR 320, in certain parts, and establish a new 21 CFR 321 to clarify FDA's study conduct expectations for clinical pharmacology, and clinical and analytical bioavailability (BA) and bioequivalence (BE) studies that support marketing applications for human drug and biological products. The proposed rule would specify needed basic study conduct requirements to enable FDA to ensure those studies are conducted appropriately and to verify the reliability of study data from those studies. This regulation would align with FDA's other good practice regulations, would also be consistent with current industry best practices, and would harmonize the regulations more closely with related international regulatory expectations.

Timetable:

Action	Date	FR Cite
NPRM	08/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Joseph Folian, Supervisory Biologist, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5215, Silver Spring, MD 20993–0002, *Phone:* 240 402–4089, *Email: brian.folian@fda.hhs.gov.*

RIN: 0910–AI57

309. Amendments to the Final Rule Regarding the List of Bulk Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act (Section 610 Review) [0910–AI70]

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 351; 21 U.S.C. 371(a); 21 U.S.C. 352; 21 U.S.C. 355

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drug products (the 503A Bulks List). The proposed rule will identify certain bulk drug substances that FDA has considered and is proposing to place on the 503A Bulks List and certain bulk drug substances that FDA has considered and is proposing not to include on the 503A Bulks List.

Timetable:

Action	Date	FR Cite
NPRM	10/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993, *Phone:* 240 402–6223, *Email: rosilend.lawson@fda.hhs.gov.*

RIN: 0910–AI70

310. Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (Section 610 Review) [0910–AI71]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 353a-1; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: The Food and Drug Administration is proposing rulemaking regarding statutory requirements under section 503A of the Federal Food, Drug, and Cosmetic Act for certain distributions of compounded human drug products. The proposed rule, if finalized, will include provisions regarding a standard memorandum of

understanding (MOU) that describes the responsibilities of a State Board of Pharmacy or other appropriate State agency that chooses to sign the standard MOU in investigating complaints related to drug products compounded in such State and distributed outside such State and in addressing the interstate distribution of inordinate amounts of compounded human drug products. It will also, if finalized, include provisions regarding the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the standard MOU. The rule, will also, if finalized, address communication with State boards pharmacy.

Timetable:

Action	Date	FR Cite
NPRM	10/00/23	

Regulatory Flexibility Analysis Required: Undetermined.

Agency Contact: Dominic Markwordt, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 5104, Silver Spring, MD 20993, *Phone:* 301 796–9349, *Email: dominic.markwordt@fda.hhs.gov.*

RIN: 0910–AI71

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

311. Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format [0910–AG27]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; . . .

Abstract: The Food and Drug Administration (FDA) is amending its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Prescription drug advertisements presented through media such as TV and radio must disclose the product's major side effects and contraindications in what is sometimes called the major statement. The rule would revise the regulation to reflect the statutory requirement that in DTC advertisements for human drugs in television or radio format, the major statement relating to side effects and contraindications of an advertised prescription drug must be presented in a clear, conspicuous, and neutral manner. This rule also establishes standards for determining whether the major statement in these advertisements is presented in the manner required.

Timetable:

Action	Date	FR Cite
NPRM	03/29/10	75 FR 15376
NPRM Comment Period End.	06/28/10	
NPRM Comment Period Re-opened.	01/27/12	77 FR 4273
NPRM Comment Period End.	02/27/12	
NPRM Comment Period Re-opened.	03/29/12	77 FR 16973
NPRM Comment Period Re-opened End.	04/09/12	
Final Rule	05/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Suzanna Boyle, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 51, Room 3214, Silver Spring, MD 20993, *Phone:* 240 402–4723, *Email: suzanna.boyle@fda.hhs.gov.*

RIN: 0910–AG27

312. Sunlamp Products; Amendment to the Performance Standard [0910–AG30]

Legal Authority: 21 U.S.C. 360ii; 21 U.S.C. 360kk; 21 U.S.C. 393; 21 U.S.C. 371

Abstract: FDA is updating the performance standard for sunlamp products and ultraviolet lamps for use in these products to improve safety, reflect new scientific information, and work towards harmonization with international standards. By harmonizing with the International Electrotechnical Commission, this rule will decrease the regulatory burden on industry and allow the Agency to take advantage of the expertise of the international committees, thereby also saving resources.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79505
NPRM Comment Period End.	03/21/16	
Final Rule	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301–796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AG30

313. Mammography Quality Standards Act [0910–AH04]

Regulatory Plan: This entry is Seq. No. 63 in part II of this issue of the **Federal Register**.

RIN: 0910–AH04

314. General and Plastic Surgery Devices: Restricted Sale, Distribution, And Use of Sunlamp Products [0910–AH14]

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This rule will apply device restrictions to sunlamp products. Sunlamp products include ultraviolet (UV) lamps and UV tanning beds and booths. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning use of sunlamp products at young ages, as well as frequently using sunlamp products, both increases the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End.	03/21/16	
Final Rule	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ian Ostermiller, Regulatory Counsel, Center for Devices and Radiological Health, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, WO 66, Room 5454, Silver Spring, MD 20993, *Phone:* 301–796–5678, *Email: ian.ostermiller@fda.hhs.gov.*

RIN: 0910–AH14

315. Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act [0910–AH81]

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353a; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: FDA has issued a regulation creating a list of bulk drug substances (active pharmaceutical ingredients) that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs (the 503A Bulks List). FDA has proposed to amend the 503A Bulks List by placing five additional bulk drug substances on the list. FDA has also identified 26 bulk drug substances that FDA has considered and proposed not to include on the 503A Bulks List. Additional substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

Timetable:

Action	Date	FR Cite
NPRM	09/05/19	84 FR 46688
NPRM Comment Period End.	12/04/19	
Final Rule	10/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Rosilend Lawson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 5197, Silver Spring, MD 20993, *Phone:* 240–402–6223, *Email: rosilend.lawson@fda.hhs.gov.*

RIN: 0910–AH81

316. Revocation of Uses of Partially Hydrogenated Oils in Foods [0910–AI15]

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 341; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371; 21 U.S.C. 379e

Abstract: In the **Federal Register** of June 17, 2015 (80 FR 34650), we published a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that partially hydrogenated oils (PHOs) are generally recognized as safe (GRAS) for any use in human food. In the **Federal Register** of May 21, 2018 (83 FR 23382), we denied a food additive petition requesting that the food additive regulations be amended to provide for the safe use of PHOs in certain food applications. We are now planning to issue a direct final rule and companion proposed rule to update our regulations to remove all mention of partially hydrogenated oils from FDA's GRAS regulations and as an optional ingredient in standards of identity. We are also revoking all prior sanctions for uses of PHOs in food.

Timetable:

Action	Date	FR Cite
Direct Final Rule	02/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Ellen Anderson, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS–265, 4300 River Road, College Park, MD 20740, *Phone:* 240–402–1309, *Email: ellen.anderson@fda.hhs.gov.*

RIN: 0910–AI15

317. Tobacco Product Standard for Characterizing Flavors in Cigars [0910–AI28]

Regulatory Plan: This entry is Seq. No. 65 in part II of this issue of the **Federal Register**.

RIN: 0910–AI28

318. Tobacco Product Standard for Menthol in Cigarettes [0910–AI60]

Regulatory Plan: This entry is Seq. No. 67 in part II of this issue of the **Federal Register**.

RIN: 0910–AI60

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

319. National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers [0910–AH11]

Legal Authority: Secs. 583 and 584 of the FD&C Act, as added by the DSCSA under Pub. L. 113–54, together with related FD&C Act authority added by the DSCSA

Abstract: The final rule establishes national standards for State licensing of prescription drug wholesale distributors and third-party logistics providers. The rulemaking also establishes a Federal system for wholesale drug distributor and third-party logistics provider licensing for use in the absence of a State licensure program.

Timetable:

Action	Date	FR Cite
NPRM	02/04/22	87 FR 6708
NPRM Comment Period End.	06/06/22	
NPRM Comment Period Extended.	05/24/22	87 FR 31439
NPRM Comment Period Extended End.	09/06/22	
Final Rule	04/00/25	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301–796–9362, *Email: aaron.weisbuch@fda.hhs.gov.*

RIN: 0910–AH11

320. Nicotine Toxicity Warnings [0910–AH24]

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 331; 21 U.S.C. 371; 21 U.S.C. 387f; . . .

Abstract: This rule would establish acute nicotine toxicity warning requirements for liquid nicotine and nicotine-containing e-liquid(s) intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. This action is intended to increase consumer awareness and knowledge of the risks of acute toxicity due to accidental nicotine exposure from nicotine-containing e-liquids in tobacco products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Laura Chilaka, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G355, Silver Spring, MD 20993, *Phone:* 877–287–1373, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AH24

321. Certain Requirements Regarding Prescription Drug Marketing (203 Amendment) [0910–AH56]

Legal Authority: Section 503 and related provisions of the FD&C Act, as amended by Pub. L. 113–54

Abstract: The final rule amends Food and Drug Administration (FDA) regulations at 21 CFR 203 to remove provisions no longer in effect and incorporate conforming changes following enactment of the Drug Supply Chain Security Act (DSCSA). The final rule amends the regulations to clarify provisions and avoid causing confusion with the new standards for wholesale distribution established by DSCSA.

Timetable:

Action	Date	FR Cite
NPRM	02/04/22	87 FR 6443
NPRM Comment Period End.	04/05/22	
Final Rule	04/00/25	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Aaron Weisbuch, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 4261, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301–796–9362, *Email: aaron.weisbuch@fda.hhs.gov.*

RIN: 0910–AH56

322. Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products [0910–AI61]

Legal Authority: 42 U.S.C. 262; 42 U.S.C. 264; 42 U.S.C. 300aa–25; 21 U.S.C. 321; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; . . .

Abstract: The proposed rule would modernize FDA's regulations on postmarketing safety reporting and pharmacovigilance for human drug and biological products, including blood and blood components, by capturing important new safety-related information, improving the quality and utility of submitted reports, and supporting enhanced alignment with internationally harmonized reporting guidelines. Among other things, the proposed rule would require the submission of certain nonclinical and clinical data to FDA in a periodic safety report, rather than the annual report. The proposed rule also would require application holders for drug products and certain biological products to establish and maintain a pharmacovigilance quality system that reflects the application holder's unique needs and that may support a more streamlined, flexible approach to satisfying certain postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	05/00/24	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice L. Weiner, Principal Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6270, Silver Spring, MD 20993–0002, *Phone:* 301–796–3475, *Fax:* 301–847–8440, *Email: janice.weiner@fda.hhs.gov.*

RIN: 0910–AI61

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

323. Requirements for Additional Traceability Records for Certain Foods [0910–AI44]

Legal Authority: sec. 204(d) of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) (21 U.S.C. 2223(d)); sec. 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(a)); sec. 361 of the Public Health Service Act (42 U.S.C. 264)

Abstract: This rule will establish additional recordkeeping requirements for entities that manufacture, process, pack, or hold foods that are designated as high-risk foods.

Completed:

Reason	Date	FR Cite
Final Rule	11/21/22	87 FR 70910
Final Action Effective.	01/20/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Katherine Vierk, *Phone:* 240–402–2122, *Email: katherine.vierk@fda.hhs.gov.*

RIN: 0910–AI44

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

324. Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS–4198) [0938–AU59]

Legal Authority: 42 U.S.C. 1395w

Abstract: This proposed rule would codify long-established Medicare Advantage and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.

Timetable:

Action	Date	FR Cite
NPRM	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jennifer Shapiro, Director, Medicare Plan Payment Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C1–13–18, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–7407, *Email: jennifer.shapiro@cms.hhs.gov.*

RIN: 0938–AU59

325. Transitional Coverage for Emerging Technologies (CMS–3421) [0938–AU86]

Regulatory Plan: This entry is Seq. No. 71 in part II of this issue of the **Federal Register**.

RIN: 0938–AU86

326. • CY 2024 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1784) (Section 610 Review) [0938–AV07]

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B including, but not limited to, establishing payment policies for dental services prior to the initiation of immunotherapy services. These changes would apply to services furnished beginning January 1, 2024. Additionally, this rule proposes updates to the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1–09–07, Baltimore, MD 21244, *Phone:* 410–786–9316, *Email: gift.tee@cms.hhs.gov.*

RIN: 0938–AV07

327. • Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2024 Rates (CMS–1785) (Section 610 Review) [0938–AV08]

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This annual proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems. In addition, the rule proposes to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	04/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AV08

328. • CY 2024 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1786) (Section 610 Review) [0938–AV09]

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This annual proposed rule would revise the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The proposed rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the ambulatory surgical center payment system list of services and rates. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	06/00/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Elise Barringer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–9222, *Email: elise.barringer@cms.hhs.gov.*

RIN: 0938–AV09

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

329. Omnibus COVID–19 Health Care Staff Vaccination (CMS–3415) (Section 610 Review) [0938–AU75]

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1302

Abstract: This interim final rule with comment period revises the infection control requirements that most Medicare- and Medicaid-participating providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of residents, clients, patients, and staff and reflect lessons learned as result of the COVID–19 public health emergency. The revisions to the infection control requirements establish COVID–19 vaccination requirements for staff at the included Medicare- and Medicaid-participating providers and suppliers.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/05/21	86 FR 61555
Interim Final Rule Effective.	11/05/21	
Interim Final Rule Comment Period End.	01/04/22	
Reviewing Public Comments.	To Be Determined	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Lauren Oviatt, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, MS: C2–21–16, 7500 Security Boulevard, Baltimore, MD 21244–1850, *Phone:* 410–786–4683, *Email: lauren.oviatt@cms.hhs.gov.*

RIN: 0938–AU75

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

330. CY 2023 Home Health Prospective Payment System Rate Update and Home Infusion Therapy Services Payment Update (CMS–1766) (Completion of a Section 610 Review) [0938–AU77]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule updates the national standardized 30-day period payment rate, national per-visit rates used to calculate low utilization payment adjustments (LUPAs), and outlier payments under the Medicare prospective payment system for home health agencies based on the applicable home health payment update percentage. This rule also updates the home infusion therapy services payment rate. These changes apply to services furnished on or after January 1, 2023.

Timetable:

Action	Date	FR Cite
NPRM	06/23/22	87 FR 37600
NPRM Comment Period End.	08/16/22	
Final Action	11/04/22	87 FR 66790
Final Rule Effective.	01/01/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Slater, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–5229, *Email: brian.slater@cms.hhs.gov.*

RIN: 0938–AU77

331. CY 2023 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (CMS–1768) (Completion of a Section 610 Review) [0938–AU79]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395d(d); 42 U.S.C. 1395f(b); 42 U.S.C. 1395g; . . .

Abstract: This annual final rule updates the bundled payment system for ESRD facilities by January 1, 2023. The rule also updates the quality incentives in the ESRD program.

Timetable:

Action	Date	FR Cite
NPRM	06/28/22	87 FR 38464
NPRM Comment Period End.	08/22/22	
Final Action	11/07/22	87 FR 67136
Final Action Effective.	01/01/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Simone Dennis, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–06–16, Baltimore, MD 21244, *Phone:* 410 786–6041, *Email: simone.dennis@cms.hhs.gov.*

RIN: 0938–AU79

332. FY 2023 Inpatient Psychiatric Facilities Prospective Payment System Rate (CMS–1769) (Completion of a Section 610 Review) [0938–AU80]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule updates the prospective payment system for inpatient psychiatric facilities (IPF) with discharges beginning on October 1, 2022.

Timetable:

Action	Date	FR Cite
NPRM	04/04/22	87 FR 19415
NPRM Comment Period End.	05/31/22	
Final Action	07/29/22	87 FR 46846
Final Action Effective.	10/01/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Nicolas Brock, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–05–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–5148, *Email: nicolas.brock@cms.hhs.gov.*

RIN: 0938–AU80

333. CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1770) (Completion of a Section 610 Review) [0938–AU81]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises payment polices under the Medicare physician fee schedule, and makes other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2023. Additionally, this rule updates the Quality Payment Program.

Timetable:

Action	Date	FR Cite
NPRM	07/29/22	87 FR 45860
NPRM Comment Period End.	09/06/22	
Final Action	11/18/22	87 FR 69404
Final Action Effective.	01/01/23	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gift Tee, Director, Division of Physician Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, 7500 Security Boulevard, MS: C1–09–07, Baltimore, MD 21244, *Phone:* 410–786–9316, *Email: gift.tee@cms.hhs.gov.*

RIN: 0938–AU81

334. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (CMS–1771) (Completion of a Section 610 Review) [0938–AU84]

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems. In addition, the rule establishes new requirements or revises existing requirements for quality reporting by specific Medicare providers.

Timetable:

Action	Date	FR Cite
NPRM	05/10/22	87 FR 28108
NPRM Comment Period End.	06/17/22	
Final Action	08/10/22	87 FR 48780
Final Action Effective.	10/01/22	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410–786–6504, *Email: donald.thompson@cms.hhs.gov.*

RIN: 0938–AU84

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