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 (EO) 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: C'Reda J. Weeden, 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, especially for those who are least able to help themselves. 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 rulemaking activities that the Department expects to undertake in the foreseeable future to advance this mission. The Agenda furthers several Departmental goals, including strengthening health care; advancing scientific knowledge and innovation; advancing the health, safety, and well-being of the American people; increasing efficiency, transparency, and accountability of HHS programs; and strengthening the Nation's health and human services infrastructure and workforce.

HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory Web page (*http://www.HHS.gov/regulations*) which includes links to HHS rules currently open for public comment, and also provides a ''regulations toolkit'' with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review Web page (*http://www.HHS.gov/RetrospectiveReview*).

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.*

Dated: September 22, 2014.

C'Reda J. Weeden,

Executive Secretary to the Department.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
275	SAMHSA User Fees for Publications	0930–AA18

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
276	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
277	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
278	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
279	Abbreviated New Drug Applications and 505(b)(2)	0910–AF97
280	Updated Standards for Labeling of Pet Food	0910–AG09
281	Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals **(Reg Plan Seq No. 48)**.	0910–AG10
282	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
283	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products.	0910–AG18
284	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption **(Reg Plan Seq No. 49)**.	0910–AG35
285	Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food **(Reg Plan Seq No. 50)**.	0910–AG36
286	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
287	Foreign Supplier Verification Program **(Reg Plan Seq No. 52)**	0910–AG64
288	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
289	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
290	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
291	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04
292	Investigational New Drug Application Annual Reporting	0910–AH07
293	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14

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

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
294	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	0910–AA49
295	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling.	0910–AF11
296	Combinations of Bronchodilators With Nasal Decongestant; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.	0910–AF33
297	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910–AF38
298	Laser Products; Amendment to Performance Standard	0910–AF87
299	''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act **(Reg Plan Seq No. 53)**.	0910–AG38
300	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
301	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines **(Reg Plan Seq No. 54)**	0910–AG56
302	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments **(Reg Plan Seq No. 55)**.	0910–AG57
303	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products **(Reg Plan Seq No. 58)**.	0910–AG94
304	Veterinary Feed Directive **(Reg Plan Seq No. 59)**	0910–AG95
305	Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.	0910–AH16

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.
306	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22
307	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs.	0910–AF23
308	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	0910–AG63
309	Sanitary Transportation of Human and Animal Food	0910–AG98

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
310	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors.	0910–AF27
311	Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements.	0910–AF96
312	Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products.	0910–AG81

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
313	Home Health Agency Conditions of Participation (CMS–3819–F) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AG81
314	Reform of Requirements for Long-Term Care Facilities (CMS–3260–P) **(Rulemaking Resulting From a Section 610 Review) (Reg Plan Seq No. 60)**.	0938–AR61
315	Medicare Shared Savings Program; Accountable Care Organizations (CMS–1461–P) **(Section 610 Review)**.	0938–AS06
316	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) **(Rulemaking Resulting From a Section 610 Review)**.	0938–AS21
317	Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–P)	0938–AS33
318	CY 2016 Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–P) **(Reg Plan Seq No. 63)**.	0938–AS40
319	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS–1632–P) **(Reg Plan Seq No. 64)**.	0938–AS41
320	CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–P) **(Reg Plan Seq No. 65)**.	0938–AS42

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CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
321	Covered Outpatient Drugs (CMS–2345–F) **(Section 610 Review)**	0938–AQ41

CENTERS FOR MEDICARE & MEDICAID SERVICES—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
322	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F).	0938–AO91
323	Adoption of Operating Rules for HIPAA Transactions (CMS–0036–IFC)	0938–AS01

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
324	Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral (CMS–1443–FC) **(Completion of a Section 610 Review)**.	0938–AR62
325	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates (CMS–1607–F) **(Completion of a Section 610 Review)**.	0938–AS11
326	CY 2015 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1612–FC) **(Section 610 Review)**.	0938–AS12
327	CY 2015 End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS–1614–F) **(Section 610 Review)**.	0938–AS13
328	CY 2015 Hospital Outpatient Prospective Payment System (PPS) Policy Changes and Payment Rates, and CY 2015 Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1613–FC) **(Section 610 Review)**.	0938–AS15
329	Extension of Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent Hospital Program Under the FY 2014 Hospital Inpatient Prospective Payment System (CMS–1599–IFC2) **(Completion of a Section 610 Review)**.	0938–AS18

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Proposed Rule Stage

275. SAMHSA User Fees for Publications

Legal Authority: 31 U.S.C. 9701; 31 U.S.C. 1111; EO 8284; EO 11541; Pub. L. 113–76

Abstract: SAMSHA is proposing to implement a modest cost recovery program to partially offset the high costs of distributing its materials to the public. This user fee would apply only to ''over-the-limit'' non-governmental orders. An ''over the limit'' order is defined as an order that exceeds either the average weight value (3.75 lbs) or the average number of copies (8). The ''non-governmental orders'' do not include: SAMHSA's Recovery Month bulk orders; orders by SAMHSA staff for meetings or conferences; and orders from ''.gov'' and ''.mil'' addresses. Therefore, it is assumed that SAMHSA would not charge shipping for orders by other Federal, State, and local government agencies. The proposed rule would implement recent legislation allowing the funds collected as part of a user fee for publications and data requests to be available to SAMHSA until expended.

Timetable:

Action	Date	FR Cite
NPRM	02/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Altman, Legislative Director, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Rockville, MD 02857, *Phone:* 240 276–2009, *Email: brian.altman@samhsa.gov.*

RIN: 0930–AA18

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

276. Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S.-Canada Regulatory Cooperation Council (RCC) as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of OTC drug monograph elements.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record.	08/25/00	65 FR 51780
Comment Period End.	11/24/00	
NPRM (Amendment) (Common Cold).	09/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF31

277. Over-the-Counter (OTC) Drug Review—Internal Analgesic Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 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; 21 U.S.C. 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 acetaminophen safety. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling).	12/26/06	71 FR 77314
NPRM Comment Period End.	05/25/07	
Final Action (Required Warnings and Other Labeling).	04/29/09	74 FR 19385
Final Action (Correction).	06/30/09	74 FR 31177
Final Action (Technical Amendment).	11/25/09	74 FR 61512
NPRM (Amendment) (Pediatric).	10/00/15	
NPRM (Amendment) (Acetaminophen).	12/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF36

278. Over–the–Counter (OTC) Drug Review—Topical Antimicrobial Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 antimicrobial agents in healthcare antiseptic products.

Timetable:

Action	Date	FR Cite
NPRM (Healthcare).	06/17/94	59 FR 31402
Comment Period End.	12/15/95	
NPRM (Consumer Hand Wash Products).	12/17/13	78 FR 76443
NPRM (Healthcare Antiseptic).	04/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AF69

279. Abbreviated New Drug Applications and 505(b)(2)

Legal Authority: Pub. L. 108–173, title XI; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: This proposed rule would make changes to certain procedures for Abbreviated New Drug Applications and related applications to patent certifications, notice to patent owners and application holders, the availability of a 30-month stay of approval, amendments and supplements, and the types of bioavailability and bioequivalence data that can be used to support these applications.

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice L. Weiner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6268, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–3601, *Fax:* 301 847–8440, *Email: janice.weiner@fda.hhs.gov.*

RIN: 0910–AF97

280. Updated Standards for Labeling of Pet Food

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 110–85, sec 1002(a)(3)

Abstract: FDA is proposing updated standards for the labeling of pet food that include nutritional and ingredient information, as well as style and formatting standards. FDA is taking this action to provide pet owners and animal health professionals more complete and consistent information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/15	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AG09

281. Current Good Manufacturing Practice and Hazard Analysis and R-Based Preventive Controls for Food for Animals

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

RIN: 0910–AG10

282. Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 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	10/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AG12

283. Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products

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

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

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Megan Velez, Policy Analyst, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4249, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–9301, *Email: megan.velez@fda.hhs.gov.*

RIN: 0910–AG18

284. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

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

RIN: 0910–AG35

285. Current Good Manufacturing and Hazard Analysis, and Risk-Based Preventive Controls for Human Food

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

RIN: 0910–AG36

286. Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives

Legal Authority: 21 U.S.C. 301 *et seq.;* 21 U.S.C. 387; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the Food and Drug Administration to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, that the Agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	05/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AG59

287. Foreign Supplier Verification Program

Regulatory Plan: This entry is Seq. No. 52 in part II of this issue of the **Federal Register**.

RIN: 0910–AG64

288. Format and Content of Reports Intended to Demonstrate Substantial Equivalence

Legal Authority: 21 U.S.C. 387e(j); 21 U.S.C. 387j(a); secs 905(j) and 910(a) of the Federal Food, Drug, and Cosmetic Act

Abstract: This regulation would establish the format and content of reports intended to demonstrate substantial equivalence. This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	07/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Gerie Voss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 301 595–1426, *Email: ctpregulations@fda.hhs.gov.*

RIN: 0910–AG96

289. Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods

Legal Authority: Sec 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

Abstract: This proposed rule would establish requirements concerning compliance for using a ''gluten-free'' labeling claim for those foods for which there is no scientifically valid analytical method available that can reliably detect and accurately quantify the presence of 20 parts per million (ppm) gluten in the food.

Timetable:

Action	Date	FR Cite
NPRM	01/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Felicia Billingslea, Director, Food Labeling and Standard Staff, Department of Health and Human Services, Food and Drug

Administration, Room 4D045, HFS 820, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1803, *Fax:* 301 436–2636, *Email: felicia.billingslea@fda.hhs.gov.*

RIN: 0910–AH00

290. Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System

Legal Authority: 21 U.S.C. 360c

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system. A CT X-ray system is a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles. High doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning. The design of a CT X-ray system should balance the benefits of the device (*i.e.,* the ability of the device to produce a diagnostic quality image) with the known risks (*e.g.,* exposure to ionizing radiation). FDA is establishing proposed special controls, which, when combined with the general controls, would provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite
NPRM	09/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Erica Blake, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6248, *Fax:* 301 847–8145, *Email: erica.blake@fda.hhs.gov.*

RIN: 0910–AH03

291. Mammography Quality Standards Act; Regulatory Amendments

Legal Authority: 21 U.S.C. 360i; 21 U.S.C. 360nn; 21 U.S.C. 374(e); 42 U.S.C. 263b

Abstract: FDA is proposing to amend its regulations governing mammography. The amendments would update the regulations issued under the Mammography Quality Standards Act of 1992 (MQSA). FDA is taking this action to address changes in mammography technology and mammography processes, such as breast density reporting, that have occurred since the regulations were published in 1997.

Timetable:

Action	Date	FR Cite
NPRM	04/00/15	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AH04

292. Investigational New Drug Application Annual Reporting

Legal Authority: 21 U.S.C. 355(i); 21 U.S.C. 371(a)

Abstract: This proposed rule would revise the requirements concerning annual reports submitted to investigational new drug applications (INDs) by replacing the current annual reporting requirement with a requirement that is consistent with the format, content, and timing of submission of the development safety update report devised by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Timetable:

Action	Date	FR Cite
NPRM	09/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Peter A. Taschenberger, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Building 51, Room 6312, Silver Spring, MD 20993, *Phone:* 301 796–0018, *Fax:* 301 847–3529, *Email: peter.taschenberger@fda.hhs.gov.*

RIN: 0910–AH07

293. General and Plastic Surgery Devices: Sunlamp Products

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

Abstract: This proposed rule would apply device restrictions to sunlamp products.

Timetable:

Action	Date	FR Cite
NPRM	03/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Paul Gadiock, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, W0–66, Room 4432, Silver Spring, MD 20993–0002, *Phone:* 301 796–5736, *Fax:* 301 847–8145, *Email: paul.gadiock@fda.hhs.gov.*

RIN: 0910–AH14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

294. Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

Legal Authority: 21 U.S.C. 321 and 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 356c; 21 U.S.C. 360 and 360b; 21 U.S.C. 360c to 360f; 21 U.S.C. 360h to 360j; 21 U.S.C. 371 and 374; 21 U.S.C. 379e and 381; 21 U.S.C. 393; 15 U.S.C. 1451 to 1561; 42 U.S.C. 262 and 264; 42 U.S.C. 271

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, including certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted. They also address National Drug Codes.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51276
NPRM Comment Period End.	02/26/07	
Final Action	10/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Joy, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, WO 51, Room 6254, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2242, *Email: david.joy@fda.hhs.gov.*

RIN: 0910–AA49

295. Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling

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

Abstract: This final rule will amend the content and format of the ''Pregnancy,'' ''Labor and delivery,'' and ''Nursing mothers'' subsections of the ''Use in Specific Populations'' section of regulations regarding the labeling for human prescription drug and biological products to better communicate risks.

Timetable:

Action	Date	FR Cite
NPRM	05/29/08	73 FR 30831
NPRM Comment Period End.	08/27/08	
Final Action	11/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathy Schreier, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., WO51, Rm. 6246, Silver Spring, MD 20993, *Phone:* 301 796–3432, *Email: kathy.schreier@fda.hhs.gov*.

RIN: 0910–AF11

296. Combinations of Bronchodilators With Nasal Decongestant; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with 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 (Oral Bronchodilator & Oral Nasal Decongestant).	07/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov*.

RIN: 0910–AF33

297. Over-the-Counter (OTC) Drug Review—Laxative Drug Products

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360 to 360a; 21 U.S.C. 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 final rule listed will address the professional labeling for sodium phosphate drug products.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium).	03/29/07	72 FR 14669
NPRM (Professional Labeling—Sodium Phosphate).	02/11/11	76 FR 7743
NPRM Comment Period End.	03/14/11	
Final Action (Professional Labeling—Sodium Phosphate).	10/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov*.

RIN: 0910–AF38

298. Laser Products; Amendment to Performance Standard

Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393

Abstract: The regulation will amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The amendment is intended to update FDA's performance standard to reflect advancements in technology.

Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End.	09/23/13	
Final Action	10/00/15	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AF87

299. ''Tobacco Products'' Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act

Regulatory Plan: This entry is Seq. No. 53 in part II of this issue of the **Federal Register**.

RIN: 0910–AG38

300. Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360i; 21 U.S.C. 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 21 U.S.C. 393; 42 U.S.C. 264; 42 U.S.C. 271; . . .

Abstract: This rule will amend FDA's regulations on acceptance of data from clinical investigations for medical devices to require that clinical investigations conducted outside the United States in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption

application, or a premarket notification submission be conducted in accordance with good clinical practice.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End.	05/28/13	
Final Action	01/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sheila Anne Brown, Policy Analyst, Investigational Device Exemptions Staff, Department of Health and Human Services, Food and Drug Administration, WO 66, Room 1651, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6563, *Fax:* 301 847–8120, *Email: sheila.brown@fda.hhs.gov*.

RIN: 0910–AG48

301. Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines

Regulatory Plan: This entry is Seq. No. 54 in part II of this issue of the **Federal Register**.

RIN: 0910–AG56

302. Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

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

RIN: 0910–AG57

303. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products

Regulatory Plan: This entry is Seq. No. 58 in part II of this issue of the **Federal Register**.

RIN: 0910–AG94

304. Veterinary Feed Directive

Regulatory Plan: This entry is Seq. No. 59 in part II of this issue of the **Federal Register**.

RIN: 0910–AG95

305. • Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 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 cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant.

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	07/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Adams-King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3713, *Fax:* 301 796–9899, *Email: janice.adams-king@fda.hhs.gov.*

RIN: 0910–AH16

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

306. Food Labeling; Revision of the Nutrition and Supplement Facts Labels

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

Abstract: FDA is amending the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. This rule will modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label.

Timetable:

Action	Date	FR Cite
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End.	10/09/03	
Second ANPRM	04/04/05	70 FR 17008
Second ANPRM Comment Period End.	06/20/05	
Third ANPRM	11/02/07	72 FR 62149
Third ANPRM Comment Period End.	01/31/08	
NPRM	03/03/14	79 FR 11879
NPRM Comment Period End.	06/02/14	
Final Action	03/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Blakeley Fitzpatrick, Interdisciplinary Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–830), HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone*: 240 402–5429, *Email*: *nutritionprogramstaff@fda.hhs.gov*.

RIN: 0910–AF22

307. Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs

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

Abstract: FDA is amending its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. This rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating certain RACCs, FDA is also amending the definition of single-serving containers; amending the label serving size for breath mints; and providing for dual-column labeling, which would provide nutrition information per serving and per container or unit, as applicable, under certain circumstances.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	03/03/14	79 FR 11989
NPRM Comment Period End.	06/02/14	
Final Action	03/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Cherisa Henderson, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone*: 240 402–5429, *Fax*: 301 436–1191, *Email*: *nutritionprogramstaff@fda.hhs.gov*.

RIN: 0910–AF23

308. Focused Mitigation Strategies To Protect Food Against Intentional Adulteration

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350g; 21 U.S.C. 350i; 21 U.S.C. 371; 21 U.S.C. 374; Pub. L. 111–353

Abstract: This rule would require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

Timetable:

Action	Date	FR Cite
NPRM	12/24/13	78 FR 78014
NPRM Comment Period Extended.	03/25/14	79 FR 16251
NPRM Comment Period End.	03/31/14	
NPRM Comment Period Extended End.	06/30/14	
Final Rule	05/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jody Menikheim, Supervisory General Health Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–005), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone*: 240 402–1864, *Fax*: 301 436–2633, *Email*: *fooddefense@fda.hhs.gov*.

RIN: 0910–AG63

309. Sanitary Transportation of Human and Animal Food

Legal Authority: 21 U.S.C. 350e; 21 U.S.C. 373; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 371; . . .

Abstract: This rule would establish requirements for shippers, carriers by motor vehicle or rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated.

Timetable:

Action	Date	FR Cite
ANPRM	04/30/10	75 FR 22713
ANPRM Comment Period End.	08/30/10	
NPRM	02/05/14	79 FR 7005
NPRM Comment Period Extended.	05/23/14	79 FR 29699
NPRM Comment Period End.	05/31/14	
NPRM Comment Period Extended End.	07/30/14	
Final Rule	03/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michael E. Kashtock, Supervisory Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone*: 240 402–2022, *Fax*: 301 346–2632, *Email*: *michael.kashtock@fda.hhs.gov*.

RIN: 0910–AG98

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

310. Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records And Reports; and Quality Factors

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 342; 21 U.S.C. 350a; 21 U.S.C. 371

Abstract: The Food and Drug Administration (FDA) is revising its infant formula regulations 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	
Interim Final Rule	02/10/14	79 FR 7934
Interim Final Rule Comment Period End.	03/27/14	
Final Action	06/10/14	79 FR 33057

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Leila Beker, Biologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–850), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1451, *Email: leila.beker@fda.hhs.gov*.

RIN: 0910–AF27

311. Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 355a; 21 U.S.C. 356 to 356c; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 375; 21 U.S.C. 379k–l; 21 U.S.C. 379aa; 21 U.S.C. 381; 42 U.S.C. 241; 42 U.S.C. 262; 42 U.S.C. 264; . . .

Abstract: The final rule would amend FDA's postmarketing safety reporting regulations for human drug and biological products to require that mandatory safety reports submitted to the Agency be transmitted in an electronic format that FDA can process, review, and archive. The rule will allow the Agency to review safety reports more quickly, to identify emerging safety problems, and disseminate safety information more rapidly in support of FDA's public health mission. The amendments also would be a key element in harmonizing FDA's postmarketing safety reporting regulations with international and International Harmonization Standards standards for the electronic submission of safety information.

Timetable:

Action	Date	FR Cite
ANPRM	11/05/98	63 FR 59746
ANPRM Comment Period End.	02/03/99	
NPRM	08/21/09	74 FR 42184
NPRM Comment Period End.	11/19/09	
Final Action	06/10/14	79 FR 33072

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Reena Raman, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6238, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–7577, *Fax:* 301 847–8440, *Email: reena.raman@fda.hhs.gov*.

RIN: 0910–AF96

312. Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Tobacco Products

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387s; Pub. L. 111–31

Abstract: This rule will require manufacturers and importers of tobacco products to submit certain market share data to FDA. USDA currently collects such data, but its program sunsets at the end of September 2014, and USDA will cease collection of this information. FDA is taking this action so that it may continue to calculate market share percentages needed to compute user fees.

Timetable:

Action	Date	FR Cite
NPRM	05/31/13	78 FR 32581
NPRM Comment Period End.	08/14/13	
Final Action	07/10/14	79 FR 39302

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Annette L. Marthaler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 877 287–1373, *Fax:* 877 287–1426, *Email: ctpregulations@fda.hhs.gov*.

RIN: 0910–AG81

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

313. Home Health Agency Conditions of Participation (CMS–3819–F) (Rulemaking Resulting From a Section 610 Review)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395x; 42 U.S.C. 1395cc(a); 42 U.S.C. 1395hh; 42 U.S.C. 1395bb

Abstract: This final rule revises the existing Conditions of Participation that Home Health Agencies must meet to participate in the Medicare program. The new 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 improve patient safety and achieve broad-based improvements in 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	10/09/14	79 FR 61163
Second NPRM Comment Period End.	12/08/14	
Final Action	10/00/17	

Regulatory Flexibility Analysis Required: No.

Agency Contact: Danielle Shearer, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards & Quality, MS: S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–6617, *Email: danielle.shearer@cms.hhs.gov*.

RIN: 0938–AG81

314. Reform of Requirements for Long-Term Care Facilities (CMS–3260–P) (Rulemaking Resulting From a Section 610 Review)

Regulatory Plan: This entry is Seq. No. 60 in part II of this issue of the **Federal Register**.

RIN: 0938–AR61

315. Medicare Shared Savings Program; Accountable Care Organizations (CMS–1461–P) (Section 610 Review)

Legal Authority: PL–111–148, sec 3022

Abstract: This proposed rule addresses changes to the Medicare Shared Savings Program (Shared Savings Program), including provisions relating to the payment of Accountable Care Organizations (ACOs) participating in the Shared Savings Program. Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee for service (FFS) payments under Parts A and B and are eligible for additional payments from the ACO if they meet specified quality and savings requirements.

Timetable:

Action	Date	FR Cite
NPRM	11/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Terri Postma, Medical Officer, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5–15–24, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4169, *Email: terri.postma@cms.hhs.gov*.

RIN: 0938–AS06

316. Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care (CMS–3295–P) (Rulemaking Resulting From a Section 610 Review)

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

Abstract: This proposed rule would update the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. These proposals are intended to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.

Timetable:

Action	Date	FR Cite
NPRM	03/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: CDR Scott Cooper, Senior Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Mail Stop S3–01–02, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9465, *Email: scott.cooper@cms.hhs.gov*.

RIN: 0938–AS21

317. • Medicare Clinical Diagnostic Laboratory Test Payment System (CMS–1621–P)

Legal Authority: Pub. L. 113–93, sec 216

Abstract: Under section 216 of the Protecting Access to Medicare Act of 2014, this proposed rule would require Medicare payment for clinical laboratory tests to be based on private payor rates beginning January 1, 2017. Beginning January 1, 2016, and every 3 years thereafter (or, annually, for certain laboratory tests), applicable laboratories must report to CMS the amount they are

paid by each private payor for a test, and the volume of such tests performed for each such payer for the period. The payment rate reported by a laboratory must reflect all discounts, rebates, coupons, and other price concessions.

Timetable:

Action	Date	FR Cite
NPRM	12/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Anne Hauswald, Director, Division of Ambulatory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C4–01–26, 7500 Security Blvd., Baltimore, MD 21244, *Phone:* 410 786–4546, *Email: anne-e-tayloe.hauswald@cms.hhs.gov*.

Valerie Miller, Deputy Director, Division of Ambulatory Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4535, *Email: valerie.miller@cms.hhs.gov*.

RIN: 0938–AS33

318. • CY 2016 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1631–P)

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

RIN: 0938–AS40

319. • Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2016 Rates (CMS–1632–P)

Regulatory Plan: This entry is Seq. No. 64 in part II of this issue of the **Federal Register**.

RIN: 0938–AS41

320. • CY 2016 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1633–P)

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

RIN: 0938–AS42

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

321. Covered Outpatient Drugs (CMS–2345–F) (Section 610 Review)

Legal Authority: Pub. L. 111– 48, secs 2501, 2503, 3301(d)(2); Pub. L. 111–152, sec 1206; Pub. L. 111–8, sec 221

Abstract: This final rule revises requirements pertaining to Medicaid reimbursement for covered outpatient drugs to implement provisions of the Affordable Care Act. This rule also revises other requirements related to covered outpatient drugs, including key aspects of Medicaid coverage, payment, and the drug rebate program.

Timetable:

Action	Date	FR Cite
NPRM	02/02/12	77 FR 5318
NPRM Comment Period End.	04/02/12	
Final Action	04/00/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Wendy Tuttle, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations, Mail Stop S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–8690, *Email: wendy.tuttle@cms.hhs.gov*.

RIN: 0938–AQ41

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Long-Term Actions

322. Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–F)

Legal Authority: 42 U.S.C. 1821; 42 U.S.C. 1861ff (3)(B)(i)(ii); 42 U.S.C. 1913(c)(1) et al

Abstract: This rule finalizes emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. This rule ensures providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

Timetable:

Action	Date	FR Cite
NPRM	12/27/13	78 FR 79082
NPRM Comment Period Extended.	02/21/14	79 FR 9872
NPRM Comment Period End.	03/31/14	
Final Action	12/00/16	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Graham, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Clincial Standards and Quality, Mail Stop S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244–1850, *Phone:* 410 786–8020, *Email: janice.graham@cms.hhs.gov*.

RIN: 0938–AO91

323. Adoption of Operating Rules for HIPAA Transactions (CMS–0036–IFC)

Legal Authority: Pub. L. 104–191, sec 1104

Abstract: Under the Affordable Care Act, this interim final rule adopts operating rules for HIPAA transactions for health care claims or equivalent encounter information, enrollment and disenrollment of a health plan, health plan premium payments, and referral certification and authorization.

Timetable:

Action	Date	FR Cite
Interim Final Rule	11/00/15	

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AS01

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

324. Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics and CLIA Enforcement Actions for Proficiency Testing Referral (CMS–1443–FC) (Completion of a Section 610 Review)

Legal Authority: Pub. L. 111–148, sec 10501

Abstract: This final rule establishes methodology and payment rates for a prospective payment system (PPS) for Federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act. This rule also establishes a policy which would allow rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and makes other technical and conforming changes to the RHC and FQHC regulations. Finally, this rule makes changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referral.

Timetable:

Action	Date	FR Cite
NPRM	09/23/13	78 FR 58386
NPRM Comment Period End.	11/18/13	
Final Rule	05/02/14	79 FR 25436
Comment Period End.	07/01/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Corinne Axelrod, Health Insurance Specialist, Hospital and Ambulatory Policy Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244, Phone: 410 786–5620, *Email: corinne.axelrod@cms.hhs.gov*.

RIN: 0938–AR62

325. Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates (CMS–1607–F) (Completion of a Section 610 Review)

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

Abstract: This 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.

Timetable:

Action	Date	FR Cite
NPRM	05/14/14	79 FR 27977
NPRM Comment Period End.	06/30/14	
Final Action	08/22/14	79 FR 49853

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Donald Thompson, Deputy 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–AS11

326. CY 2015 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS–1612–FC) (Section 610 Review)

Legal Authority: Social Security Act, secs 1102, 1871 and 1848

Abstract: This final rule addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

Timetable:

Action	Date	FR Cite
NPRM	07/11/14	79 FR 40318
NPRM Comment Period End.	09/02/14	
Final Action	11/13/14	79 FR 67548

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathy Bryant, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–01–27, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–3448, *Email: kathy.bryant@cms.hhs.gov*.

RIN: 0938–AS12

327. CY 2015 End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (CMS–1614–F) (Section 610 Review)

Legal Authority: Social Security Act, sec 1834(a)(1)(6); MIPPA, sec 153(b)

Abstract: This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. This rule also sets forth requirements for the ESRD quality incentive program (QIP), including payment years (PYs) 2017 and 2018. This rule also makes a technical correction to remove outdated terms and definitions. In addition, this rule sets forth the methodology for adjusting Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule payment amounts using information from the Medicare DMEPOS Competitive Bidding Program (CBP); makes alternative payment rules for DME and enteral nutrition under the Medicare DMEPOS CBP; clarifies the statutory Medicare hearing aid coverage exclusion and specifies devices not subject to the hearing aid exclusion; updates the definition of minimal self-adjustment regarding what specialized training is needed by suppliers to provide custom fitting services if they are not certified orthotists; clarifies the Change of Ownership (CHOW) and provides for an exception to the current requirements; revises the appeal provisions for termination of a contract and notification to beneficiaries under the Medicare DMEPOS CBP, and adds a technical change related to submitting bids for infusion drugs under the Medicare DMEPOS CBP.

Timetable:

Action	Date	FR Cite
NPRM	07/11/14	79 FR 40208
NPRM Comment Period End.	09/02/14	
Final Action	11/06/14	79 FR 66120
Final Action Effective.	01/01/15	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Michelle Cruse, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, Mail Stop C5–05–27, 7500 Security Boulevard, Baltimore,

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RIN: 0938–AS13

328. CY 2015 Hospital Outpatient Prospective Payment System (PPS) Policy Changes and Payment Rates, and CY 2015 Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS–1613–FC) (Section 610 Review)

Legal Authority: sec 1833 of the Social Security Act

Abstract: This final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2015 to implement applicable statutory requirements and changes arising from our continuing experience with these systems. In this rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program.

Timetable:

Action	Date	FR Cite
NPRM	07/14/14	79 FR 40916
NPRM Comment Period End.	09/02/14	
Final Action	11/13/14	79 FR 66770
Final Action Effective.	01/01/15	

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AS15

329. Extension of Payment Adjustment for Low-Volume Hospitals and the Medicare-Dependent Hospital Program Under the FY 2014 Hospital Inpatient Prospective Payment System (CMS–1599–IFC2) (Completion of a Section 610 Review)

Legal Authority: Pub. L. 113–67, secs 1105 and 1106

Abstract: This interim final rule implements changes to the payment adjustment for low-volume hospitals and to the Medicare-dependent hospital program under the hospital inpatient prospective payment systems for FY 2014 (through March 31, 2014) in accordance with sections 1105 and 1106, respectively, of the Pathway for SGR Reform Act of 2013.

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/18/14	79 FR 15022
Interim Final Rule Comment Period End.	05/12/14	
Merged With 0938–AS11.	06/01/14	

Regulatory Flexibility Analysis Required: Yes.

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