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 12866 require the Department semiannually to issue an inventory of rulemaking actions under development to provide the public a summary of forthcoming regulatory actions. This information will help the public more effectively participate in the Department's regulatory activity, and the Department welcomes comments on any aspect of this agenda.

FOR FURTHER INFORMATION CONTACT: Jennifer M. Cannistra, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal Government's principal 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.

The purpose of the agenda is to encourage more effective public participation in the regulatory process. HHS is currently furthering this goal by engaging in a Department-wide effort to identify ways to make the rulemaking process more accessible to the general public. This effort is in response to President Obama's January 18, 2011, Executive Order 13563, ''Improving Regulation and Regulatory Review,'' which requires ongoing retrospective review of current agency regulations and encourages federal agencies to develop balanced regulations through a process that ''allows for public participation and an open exchange of ideas.'' HHS's efforts include stakeholder outreach and continuing to update its main regulatory Web page (*http://www.HHS.gov/Regulations*) with information helpful to the public. For example, to encourage public participation, the Web page includes links to HHS rules currently open for public comment and provides a ''regulations toolkit'' with background information on regulations, the commenting process, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in retrospective review and rulemaking through education and outreach (*http://www.HHS.gov/RetrospectiveReview*).

The rulemaking abstracts included in this paper issue of the **Federal Register** only 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: April 22, 2013.

Jennifer M. Cannistra,

Executive Secretary to the Department.

FOOD AND DRUG ADMINISTRATION—PRERULE STAGE

Sequence No.	Title	Regulation Identifier No.
1	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910–AF43
2	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures **(Section 610 Review)**.	0910–AG14

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
3	Food Labeling; Revision of the Nutrition and Supplement Facts Labels	0910–AF22
4	Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed.	0910–AF23
5	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
6	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910–AF36
7	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910–AF69
8	Laser Products; Proposed Amendment to Performance Standard	0910–AF87
9	Updated Standards for Labeling of Pet Food	0910–AG09
10	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.	0910–AG10
11	Over-the-Counter (OTC) Drug Review—Pediatric Dosing for Cough/Cold Products	0910–AG12
12	Electronic Distribution of Prescribing Information for Human Prescription Drugs Including Biological Products.	0910–AG18
13	Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Second Phase.	0910–AG20
14	Produce Safety Regulation	0910–AG35
15	Hazard Analysis and Risk-Based Preventive Controls	0910–AG36

FOOD AND DRUG ADMINISTRATION—PROPOSED RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
16	"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act.	0910–AG38
17	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
18	Foreign Supplier Verification Program	0910–AG64
19	Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components.	0910–AG70
20	Requirements for the Submission of Data Needed to Calculate User Fees for Manufacturers and Importers of Tobacco Products.	0910–AG81
21	Food Labeling: Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies and Breath Mints.	0910–AG82
22	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
23	Veterinary Feed Directive	0910–AG95
24	Format and Content of Reports Intended to Demonstrate Substantial Equivalence	0910–AG96
25	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
26	Mammography Quality Standards Act; Regulatory Amendments	0910–AH04

FOOD AND DRUG ADMINISTRATION—FINAL RULE STAGE

Sequence No.	Title	Regulation Identifier No.
27	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling.	0910–AF11
28	Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors.	0910–AF27
29	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910–AF33
30	Unique Device Identification	0910–AG31
31	Food Labeling: Calorie Labeling of Articles of Food Sold in Vending Machines	0910–AG56
32	Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments.	0910–AG57
33	Use of Certain Symbols in Labeling	0910–AG74
34	Food Labeling; Gluten-Free Labeling of Foods	0910–AG84

FOOD AND DRUG ADMINISTRATION—LONG-TERM ACTIONS

Sequence No.	Title	Regulation Identifier No.
35	Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices	0910–AG48

FOOD AND DRUG ADMINISTRATION—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
36	Food Labeling: Serving Sizes; Reference Amounts for Candies	0910–AG83

CENTERS FOR MEDICARE & MEDICAID SERVICES—PROPOSED RULE STAGE

Sequence No.	Title	Regulation Identifier No.
37	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–P) **(Section 610 Review)**.	0938–AO91
38	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2014 (CMS–1601–P).	0938–AR54
39	Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS–1600–P).	0938–AR56
40	Prospective Payment System for Federally Qualified Health Centers (FQHCs) (CMS–1443–P) **(Section 610 Review)**.	0938–AR62

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE

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

CENTERS FOR MEDICARE & MEDICAID SERVICES—FINAL RULE STAGE—Continued

Sequence No.	Title	Regulation Identifier No.
42	Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2014 (CMS–1599–F).	0938–AR53

CENTERS FOR MEDICARE & MEDICAID SERVICES—COMPLETED ACTIONS

Sequence No.	Title	Regulation Identifier No.
43	Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS–5060–F)	0938–AR33
44	Part B Inpatients Billings in Hospitals (CMS–1455–F)	0938–AR73

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Prerule Stage

1. Over-the-Counter (OTC) Drug Review—Sunscreen 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. The first of the future actions will address the safety of sunscreen active ingredients.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent).	02/22/07	72 FR 7941
ANPRM Comment Period End.	05/23/07	
NPRM (UVA/UVB).	08/27/07	72 FR 49070
NPRM Comment Period End.	12/26/07	
Final Action (UVA/UVB).	06/17/11	76 FR 35620
NPRM (Effectiveness).	06/17/11	76 FR 35672
NPRM (Effectiveness) Comment Period End.	09/15/11	
ANPRM (Dosage Forms).	06/17/11	76 FR 35669
ANPRM (Dosage Forms) Comment Period End.	09/15/11	
ANPRM (Safety)	11/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2773, *Fax:* 301 796–9899, *Email: david.eng@fda.hhs.gov.*

RIN: 0910–AF43

2. Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures (Section 610 Review)

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 333; 21 U.S.C. 351 to 353; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381

Abstract: FDA is currently reviewing regulations promulgated under the Prescription Drug Marketing Act (PDMA). FDA is undertaking this review to determine whether the regulations should be changed or rescinded to minimize adverse impacts on a substantial number of small entities. FDA has extended again the completion date by 1 year and will complete the review by November 2013.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation.	11/24/08	
End Review of Current Regulation.	11/00/13	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AG14

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Proposed Rule Stage

3. 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 proposing to amend 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. If finalized, 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	11/00/13	

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:* 240 402–1450, *Email: blakeley.fitzpatrick@fda.hhs.gov.*

RIN: 0910–AF22

4. Serving Sizes of Foods That Can Reasonably Be Consumed in One Eating Occasion; Dual Column Labeling; Updating, Modifying and Establishing Certain Reference Amounts Customarily Consumed

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

Abstract: FDA is proposing to amend its labeling regulations for foods to provide updated Reference Amounts Customarily Consumed (RACCs) for certain food categories. If finalized, 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 considering amending the definition of single-serving containers and providing for dual-column labeling, which would provide nutrition information per serving and per container, for certain containers.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	11/00/13	

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:* 202 402–1450, *Fax:* 301 436–1191, *Email: cherisa.henderson@fda.hhs.gov.*

RIN: 0910–AF23

5. 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).	11/00/13	

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

6. 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) (Acetaminophen).	12/00/13	
NPRM (Amendment) (Pediatric).	12/00/13	

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

7. 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 consumer hand wash 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).	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: David Eng, Regulatory Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5487, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–2773, *Fax:* 301 796–9899, *Email: david.eng@fda.hhs.gov.*

RIN: 0910–AF69

8. Laser Products; Proposed Amendment to Performance Standard

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

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

performance standard to reflect advancements in technology.

Timetable:

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

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

9. 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 useful information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/14	

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

10. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350c; 21 U.S.C. 350d note; 21 U.S.C. 350g; 21 U.S.C. 350g note; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 264; 42 U.S.C. 243; 42 U.S.C. 271; . . .

Abstract: FDA is proposing regulations for preventive controls for animal food, including ingredients and mixed animal feed. This action is intended to provide greater assurance that food marketed for all animals, including pets, is safe.

Timetable:

Action	Date	FR Cite
NPRM	08/00/13	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AG10

11. 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	11/00/13	

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

12. 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	10/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janet Norden, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6324, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–2500, *Email: janet.norden@fda.hhs.gov.*

RIN: 0910–AG18

13. Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Second Phase

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: FDA will revise regulations for ''current good manufacturing practice'' for oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products. This revision will update and harmonize requirements and improve detection and response to emerging product safety and quality signals.

Timetable:

Action	Date	FR Cite
NPRM	01/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Paula Katz, Regulatory Counsel, Office of Compliance, Department of Health and Human Services, Food and Drug

Administration, Center for Drug Evaluation and Research, WO 51, Room 4314, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6972, *Fax:* 301 847–8742, *Email: paula.katz@fda.hhs.gov.*

RIN: 0910–AG20

14. Produce Safety Regulation

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 350h; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353 (signed on Jan. 4, 2011)

Abstract: FDA is proposing to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. The purpose of the proposed rule is to reduce the risk of illness associated with fresh produce.

Timetable:

Action	Date	FR Cite
NPRM	01/16/13	78 FR 3503
NPRM Comment Period End.	05/16/13	
NPRM Comment Period Extended.	04/26/13	78 FR 24692
NPRM Comment Period Extended End.	09/16/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Samir Assar, 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:* 240 402–1636, *Email: samir.assar@fda.hhs.gov.*

RIN: 0910–AG35

15. Hazard Analysis and Risk-Based Preventive Controls

Legal Authority: 21 U.S.C. 342; 21 U.S.C. 371; 42 U.S.C. 264; Pub. L. 111–353 (signed on Jan. 4, 2011)

Abstract: This proposed rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility. This action is intended to prevent or, at a minimum, quickly identify foodborne pathogens before they get into the food supply.

Timetable:

Action	Date	FR Cite
NPRM	01/16/13	78 FR 3646
NPRM Comment Period Extended.	04/26/13	78 FR 24691
NPRM Comment Period End.	09/16/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Jenny Scott, Senior Advisor, Department of Health and Human Services, Food and Drug Administration, Office of Food Safety, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1488, *Email: jenny.scott@fda.hhs.gov.*

RIN: 0910–AG36

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

Legal Authority: 21 U.S.C. 301 *et seq.,* The Federal Food, Drug, and Cosmetic Act; Pub. L. 111–31, The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides the Food and Drug Administration (FDA) authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the FD&C Act. This proposed rule would deem products meeting the statutory definition of ''tobacco product'' to be subject to the FD&C Act and would specify additional restrictions.

Timetable:

Action	Date	FR Cite
NPRM	10/00/13	

Regulatory Flexibility Analysis Required: Yes.

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

RIN: 0910–AG38

17. 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	12/00/13	

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, 9200 Corporate Boulevard, Room 240 H, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email: carol.drew@fda.hhs.gov.*

RIN: 0910–AG59

18. Foreign Supplier Verification Program

Legal Authority: 21 U.S.C. 384a; title III, sec 301 of FDA Food Safety Modernization Act, Pub. L. 111–353, establishing sec 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Abstract: FDA is proposing regulations that describe what a food importer must do to verify that its foreign suppliers produce food that is as safe as food produced in the United States. FDA is taking this action to improve the safety of food that is imported into the United States.

Timetable:

Action	Date	FR Cite
NPRM	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian L. Pendleton, Senior Policy Advisor, Department of Health and Human Services, Food and Drug Administration, Office of Policy, WO 32, Room 4245, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002, *Phone:* 301 796–4614, *Fax:* 301 847–8616, *Email: brian.pendleton@fda.hhs.gov.*

RIN: 0910–AG64

19. Amendments to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals—Components

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 360bbb–7; 21 U.S.C. 371; 21 U.S.C. 374; 42 U.S.C. 262; 42 U.S.C. 264

Abstract: FDA will revise regulations for ''current good manufacturing practice'' with regard to the control over components used in manufacturing finished pharmaceuticals.

Timetable:

Action	Date	FR Cite
NPRM	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Brian Hasselbalch, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 4364, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3279, *Email: brian.hasselbalch@fda.hhs.gov.*

Paula Katz, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 1320, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–6972, *Email: paula.katz@fda.hhs.gov.*

RIN: 0910–AG70

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

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

Abstract: FDA is proposing to 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	

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, Room 340K, 9200 Corporate Boulevard, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–3904, *Email: annette.marthaler@fda.hhs.gov.*

RIN: 0910–AG81

21. Food Labeling: Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies and Breath Mints

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

Abstract: FDA is proposing to change the nutrition label serving size for breath mints to one unit. FDA is taking this action in response to a citizen petition that requested a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion and comments received on an advance notice of proposed rulemaking published in 2005.

Timetable:

Action	Date	FR Cite
NPRM	12/30/97	62 FR 67775
NPRM Comment Period End.	03/16/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
NPRM	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–1450, *Fax:* 301 436–1191, *Email: mark.kantor@fda.hhs.gov.*

RIN: 0910–AG82

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

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 371; 42 U.S.C. 262; . . .

Abstract: This proposed rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change. The proposed rule would describe the process by which information regarding a ''changes being effected'' (CBE) labeling supplement submitted by an NDA or ANDA holder would be made publicly available during FDA's review of the labeling change. The proposed rule also would clarify requirements for the NDA holder for the reference listed drug and all ANDA holders to submit conforming labeling revisions after FDA has taken an action on the NDA and/or ANDA holder's CBE labeling supplement. These proposed revisions to FDA's regulations would create parity between NDA holders and ANDA holders with respect to submission of CBE labeling supplements.

Timetable:

Action	Date	FR Cite
NPRM	09/00/13	

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 6304, 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–AG94

23. • Veterinary Feed Directive

Legal Authority: 21 U.S.C. 354; 21 U.S.C. 360b; 21 U.S.C. 360ccc; 21 U.S.C. 360ccc–1; 21 U.S.C. 371

Abstract: The Animal Drug Availability Act created a new category of products called veterinary feed directive drugs (VFD drugs). This rulemaking is intended to provide for the increased efficiency of the VFD program.

Timetable:

Action	Date	FR Cite
ANPRM	03/29/10	75 FR 15387
ANPRM Comment Period End.	06/28/10	
NPRM	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sharon Benz, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2648, HFV–220, 7529 Standish Place, Rockville, MD 20855, *Phone:* 240 453–6864, *Email: sharon.benz@fda.hhs.gov.*

RIN: 0910–AG95

24. • 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 and compliance with the FD&C Act (sections 905(j) and 910(a) of the FD&C Act). This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	06/00/14	

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, 9200 Corporate Boulevard, Rockville, MD 20850, *Phone:* 877 287–1373, *Fax:* 240 276–4193, *Email: gerie.voss@fda.hhs.gov.*

RIN: 0910–AG96

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

Legal Authority: 21 U.S.C. 360

Abstract: The proposed rule would establish special controls for the computed tomography (CT) x-ray system, a class II device as defined in 21 CFR 892.1750. 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, or, in extremely high doses, radiation poisoning. Therefore, the design of a CT x-ray system needs to 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 special controls, combined with the general controls, to provide reasonable assurance of the safety and effectiveness of a class II CT x-ray system.

Timetable:

Action	Date	FR Cite
NPRM	12/00/13	

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

26. • 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	12/00/13	

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Final Rule Stage

27. 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 (21 CFR 201.56 and 201.57) 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	01/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Molly Flannery, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6246, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–3543, *Email: molly.flannery@fda.hhs.gov.*

RIN: 0910–AF11

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

Timetable:

Action	Date	FR Cite
NPRM	07/09/96	61 FR 36154
NPRM Comment Period End.	12/06/96	
NPRM Comment Period Re-opened.	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 Re-opened.	08/01/06	71 FR 43392
NPRM Comment Period End.	09/15/06	
Final Rule	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Benson Silverman, Staff Director, Infant Formula and Medical Foods, 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:* 240 402–1459, *Email: benson.silverman@fda.hhs.gov.*

RIN: 0910–AF27

29. Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) 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 cough/cold drug products containing an oral bronchodilator (ephedrine and its salts) in combination with any expectorant or any oral nasal decongestant.

Timetable:

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

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

30. Unique Device Identification

Legal Authority: 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 360; 21 U.S.C. 360h; 21 U.S.C. 360i; 21 U.S.C. 360j; 21 U.S.C. 360l; 21 U.S.C. 371

Abstract: FDA is issuing a final rule establishing a unique device identification system for medical devices. A unique device identification system would allow healthcare professionals and others to rapidly and precisely identify a device and obtain important information concerning the device and would reduce medical errors.

Timetable:

Action	Date	FR Cite
NPRM	07/10/12	77 FR 40735
NPRM Comment Period End.	11/07/12	
Second NPRM	11/19/12	77 FR 69393
Second NPRM Comment Period End.	12/19/13	
Final Action	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: John J. Crowley, Senior Advisor for Patient Safety, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 2315, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 980–1936, *Email: jay.crowley@fda.hhs.gov.*

RIN: 0910–AG31

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

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

Abstract: FDA published a proposed rule to establish requirements for nutrition labeling of certain food items sold in certain vending machines. FDA also proposed the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements. FDA is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19238
NPRM Comment Period End.	07/05/11	
Final Action	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Daniel Reese, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–2126, *Email: daniel.reese@fda.hhs.gov.*

RIN: 0910–AG56

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

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

Abstract: FDA published a proposed rule in the **Federal Register** to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA also proposed the terms and conditions for restaurants and similar retail food establishments registering to voluntarily be subject to the Federal requirements. FDA is issuing a final rule, and taking this action to carry out section 4205 of the Patient Protection and Affordable Care Act.

Timetable:

Action	Date	FR Cite
NPRM	04/06/11	76 FR 19192
NPRM Comment Period End.	07/05/11	
Final Action	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Daniel Reese, Food Technologist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–820), 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:* 240 402–2126, *Email: daniel.reese@fda.hhs.gov.*

RIN: 0910–AG57

33. Use of Certain Symbols in Labeling

Legal Authority: sec 502(c) of the Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 352(c); sec 514(c) of FD&C Act, 21 U.S.C. 360d(c), enacted by the Food and Drug Modernization Act of 1997 (FDAMA)

Abstract: The purpose of this rule is to allow for the inclusion of certain stand-alone symbols contained in a standard that FDA recognizes, provided that such symbols are explained in a symbols glossary that contemporaneously accompanies the medical device.

Timetable:

Action	Date	FR Cite
NPRM	04/19/13	78 FR 23508
NPRM Comment Period End.	06/18/13	
Final Action	04/00/14	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mary Follette Story, Human Factors and Accessible Medical Technology Specialist, Department of Health and Human Services, Food and

Drug Administration, Center for Devices and Radiological Health, Room 2553, 10903 New Hampshire Avenue, Silver Spring, MD 20993, *Phone:* 301 796–1456, *Email: molly.story@fda.hhs.gov.*

RIN: 0910–AG74

34. Food Labeling; Gluten-Free Labeling of Foods

Legal Authority: title II of Pub. L. 108–282; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 343; 21 U.S.C. 348; 21 U.S.C. 371

Abstract: FDA is amending its regulations to define the term ''gluten-free'' for voluntary use in the labeling of foods. FDA is taking this action to assist persons who have celiac disease to more easily identify foods that they can eat while following a ''gluten-free'' diet.

Timetable:

Action	Date	FR Cite
NPRM	01/23/07	72 FR 2795
NPRM Comment Period End.	04/23/07	
NPRM Comment Period Re-opened.	08/03/11	76 FR 46671
NPRM Comment Period Re-opened End.	10/03/11	
Final Action	07/00/13	

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–AG84

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Long-Term Actions

35. Human Subject Protection; Acceptance of Data From Clinical Studies 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 studies conducted in support of a premarket approval application, humanitarian device exemption application, an investigational device exemption application, or a premarket notification submission for a medical device.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End.	05/28/13	
Final Action	09/00/14	

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Food and Drug Administration (FDA)

Completed Actions

36. Food Labeling: Serving Sizes; Reference Amounts for Candies

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

Abstract: FDA is proposing to change its serving size regulations to provide updated Reference Amounts Customarily Consumed for candies. FDA is taking this action in response to comments received on an advance notice of proposed rulemaking published in 2005. This RIN is being withdrawn from the Unified Agenda and merged with RIN 0910–AG82.

Timetable:

Action	Date	FR Cite
NPRM	01/08/98	63 FR 1078
NPRM Comment Period End.	02/09/98	
ANPRM	04/05/05	70 FR 17010
ANPRM Comment Period End.	06/20/05	
Withdrawn	03/11/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Mark Kantor, Nutritionist, Department of Health and Human Services, Food and Drug Administration, HFS–830, 5100 Paint Branch Parkway, College Park, MD 20740, *Phone:*, 240 402–1450, *Fax:* 301 436–1191, *Email: mark.kantor@fda.hhs.gov.*

RIN: 0910–AG83

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Proposed Rule Stage

37. Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS–3178–P) (Section 610 Review)

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

Abstract: This rule proposes 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 would ensure 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	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Janice Graham, Health Insurance Specialist, Clincal Standards Group, 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

38. Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2014 (CMS–1601–P)

Legal Authority: sec 1833 of the Social Security Act

Abstract: This proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The proposed rule also 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.

Timetable:

Action	Date	FR Cite
NPRM	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Marjorie Baldo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare Management, Mail Stop C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–4617, *Email: marjorie.baldo@cms.hhs.gov.*

RIN: 0938–AR54

39. Revisions to Payment Policies Under the Physician Fee Schedule and Medicare Part B for CY 2014 (CMS–1600–P)

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

Abstract: This proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would be applicable to services furnished on or after January 1 annually.

Timetable:

Action	Date	FR Cite
NPRM	07/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Kathy Bryant, Deputy 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–AR56

40. Prospective Payment System for Federally Qualified Health Centers (FQHCS) (CMS–1443–P) (Section 610 Review)

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

Abstract: The Affordable Care Act amends the current Medicare FQHC payment policy by requiring the establishment of a new payment system, effective with cost reporting periods beginning on or after October 1, 2014. This rule proposes the establishment of the new prospective payment system.

Timetable:

Action	Date	FR Cite
NPRM	09/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Sarah Harding, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–01–26, 7500 Security Boulevard, Windsor Mill, MD 21244, *Phone:* 410 786–4001, *Email: sarah.harding@cms.hhs.gov.*

RIN: 0938–AR62

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Final Rule Stage

41. 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	01/00/14	

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

42. Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2014 (CMS–1599–F)

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

Abstract: This annual 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	05/10/13	78 FR 27485
NPRM Comment Period End.	06/25/13	
Final Action	08/00/13	

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Roechel Kujawa, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4–07–07, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 410 786–9111, *Email: roechel.kujawa@cms.hhs.gov.*

RIN: 0938–AR53

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services (CMS)

Completed Actions

43. Transparency Reports and Reporting of Physician Ownership of Investment Interests (CMS–5060–F)

Legal Authority: Pub. L. 111–148, sec 6002

Abstract: This final rule requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid, or CHIP to annually report to the Secretary certain payments or transfers of value provided to physicians or teaching hospitals (covered recipients). In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to annually report certain physician ownership or investment interests.

Timetable:

Action	Date	FR Cite
NPRM	12/19/11	76 FR 78742
NPRM Comment Period End.	02/17/12	
Final Action	02/08/13	78 FR 9457

Regulatory Flexibility Analysis Required: Yes.

Agency Contact: Niall Brennan, Director, Policy and Data Analysis Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, *Phone:* 202 690–6627, *Email: niall.brennan@cms.hhs.gov.*

RIN: 0938–AR33

44. Part B Inpatients Billings in Hospitals (CMS–1455–F)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; 42 U.S.C. 1395rr (b)(1)

Abstract: This final rule revises Medicare Part B billings policies when a Part A claim for a hospital inpatient admission is denied as not medically reasonable and necessary.

Timetable:

Action	Date	FR Cite
NPRM	03/18/13	78 FR 16632
NPRM Comment Period End.	05/17/13	
Merged With 0938–AR53.	04/23/13	

Regulatory Flexibility Analysis Required: Yes.

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RIN: 0938–AR73

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