



Federal Register

**Monday,
December 10, 2007**

Part VII

**Department of
Health and Human
Services**

Semiannual Regulatory Agenda

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

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

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order 12866 require issuance of the following inventory of the rulemaking actions being developed by the Department. The purpose is to encourage public participation in the regulatory process by providing, at as early a stage as possible, summarized information about regulatory actions under consideration.

FOR FURTHER INFORMATION CONTACT: Ann C. Agnew, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The capsulized information provided presents for public scrutiny a forecast of the rulemaking activities that the Department expects to undertake over

the foreseeable future. We focus primarily on those areas of work expected to result in publication of Notices of Proposed Rulemaking or Final Rules within the next 12 months.

For this edition of the Department of Health and Human Services' regulatory agenda, the most important significant regulatory actions and a Statement of Regulatory Priorities are included in The Regulatory Plan, which appears in both the online Unified Agenda and in part II of the **Federal Register** that includes the Unified Agenda.

In addition, beginning with the fall 2007 edition, the Internet will be the basic means for disseminating the Unified Agenda. The complete Unified Agenda will be available online at www.reginfo.gov, in a format that offers users a greatly enhanced ability to obtain information from the Agenda database.

Because publication in the **Federal Register** is mandated for the regulatory flexibility agendas required by the Regulatory Flexibility Act (5 U.S.C. 602), the Department of Health and Human Services' printed agenda entries include only:

(1) rules that are in the Agency's regulatory flexibility agenda, in accordance with the Regulatory Flexibility Act, because they are likely

to have a significant economic impact on a substantial number of small entities; and

(2) any rules that the Agency has identified for periodic review under section 610 of the Regulatory Flexibility Act.

Printing of these entries is limited to fields that contain information required by the Regulatory Flexibility Act's Agenda requirements. Additional information on these entries is available in the Unified Agenda published on the Internet. In addition, for fall editions of the Agenda, the entire Regulatory Plan will continue to be printed in the **Federal Register**, as in past years, including the Health and Human Services' Regulatory Plan.

We welcome the views of all concerned with regard to these planned rulemakings. Comments may be directed to the agency officials cited in each of the summaries below; if early attention at the Secretary's level appears needed, comments should be sent to: Ann C. Agnew, Executive Secretary to the Department, Room 603H, 200 Independence Avenue SW., Washington, DC 20201.

Dated: September 26, 2007.

Ann C. Agnew,
Executive Secretary to the Department.

Substance Abuse and Mental Health Services Administration—Proposed Rule Stage

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

Centers for Disease Control and Prevention—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
312	Control of Communicable Diseases, Interstate and Foreign Quarantine (Reg Plan Seq No. 37)	0920-AA12

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

Food and Drug Administration—Prerule Stage

Sequence Number	Title	Regulation Identifier Number
313	Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients (Section 610 Review) ...	0910-AF75
314	Medical Devices: Classification/Reclassification; Restricted Devices; Analyte Specific Reagents (Section 610 Review)	0910-AF76

HHS

Food and Drug Administration—Prerule Stage (Continued)

Sequence Number	Title	Regulation Identifier Number
315	Amended Economic Impact Analysis of Final Rule on User Labeling on Natural Rubber-Containing Medical Device (Section 610 Review)	0910-AF77
316	Financial Disclosure by Clinical Investigators (Section 610 Review)	0910-AF79
317	Beverages: Bottled Water (Section 610 Review)	0910-AF80
318	Food Labeling; Nutrient Content Claims: Definition for “High Potency” and Definition of “Antioxidant” for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods (Section 610 Review)	0910-AF83

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
319	Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics (Reg Plan Seq No. 38)	0910-AC52
320	Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling (Reg Plan Seq No. 39)	0910-AF11
321	Over-the-Counter (OTC) Drug Review—External Analgesic Products	0910-AF35
322	Over-the-Counter (OTC) Drug Review—Internal Analgesic Products	0910-AF36
323	Over-the-Counter (OTC) Drug Review—Oral Health Care Products	0910-AF40
324	Over-the-Counter (OTC) Drug Review—Sunscreen Products	0910-AF43
325	Label Requirement for Food That Has Been Refused Admission Into the United States (Reg Plan Seq No. 40)	0910-AF61
326	Over-the-Counter (OTC) Drug Review—Poison Treatment Drug Products	0910-AF68
327	Over-the-Counter (OTC) Drug Review—Topical Antimicrobial Drug Products	0910-AF69
328	Over-the-Counter (OTC) Drug Review—Urinary Analgesic Drug Products	0910-AF70

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 Number	Title	Regulation Identifier Number
329	Safety Reporting Requirements for Human Drug and Biological Products	0910-AA97
330	Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements (Reg Plan Seq No. 43)	0910-AB88
331	Prevention of Salmonella Enteritidis in Shell Eggs (Reg Plan Seq No. 44)	0910-AC14
332	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drugs	0910-AC35
333	Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910-AC55
334	Cochineal Extract and Carmine Label Declaration	0910-AF12
335	Charging for Investigational Drugs	0910-AF13
336	Expanded Access to Investigational Drugs for Treatment Use (Reg Plan Seq No. 46)	0910-AF14
337	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910-AF31
338	Over-the-Counter (OTC) Drug Review—Cough/Cold (Bronchodilator) Products	0910-AF32
339	Over-the-Counter (OTC) Drug Review—Cough/Cold (Combination) Products	0910-AF33
340	Over-the-Counter (OTC) Drug Review—Cough/Cold (Nasal Decongestant) Products	0910-AF34
341	Over-the-Counter (OTC) Drug Review—Labeling of Drug Products for OTC Human Use	0910-AF37
342	Over-the-Counter (OTC) Drug Review—Laxative Drug Products	0910-AF38
343	Over-the-Counter (OTC) Drug Review—Skin Protectant Products	0910-AF42
344	Over-the-Counter (OTC) Drug Review—Vaginal Contraceptive Products	0910-AF44
345	Over-the-Counter (OTC) Drug Review—Weight Control Products	0910-AF45
346	Substances Prohibited From Use in Animal Food or Feed To Prevent the Transmission of Bovine Spongiform Encephalopathy	0910-AF46
347	Over-the-Counter (OTC) Drug Review—Antacid Products	0910-AF52
348	Over-the-Counter (OTC) Drug Review—Skin Bleaching Products	0910-AF53

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

HHS

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
349	Requirements for Submission of In Vivo Bioequivalence Data	0910-AC23
350	Health Claims	0910-AF09
351	Over-the-Counter (OTC) Drug Review—Ophthalmic Products	0910-AF39
352	Over-the-Counter (OTC) Drug Review—Overindulgence in Food and Drink Products	0910-AF51
353	Over-the-Counter (OTC) Drug Review—Stimulant Drug Products	0910-AF56
354	Over-the-Counter Antidiarrheal Drug Products	0910-AF63
355	Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin (Section 610 Review)	0910-AF99

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
356	Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality Systems Regulations (Completion of a Section 610 Review)	0910-AF71
357	Package Size Limitation for Sodium Phosphates Oral Solution and Warning and Direction Statements for Oral and Rectal Sodium Phosphates for Over-the-Counter Laxative Use (Section 610 Review)	0910-AF73
358	Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use: Required Alcohol Warning (Section 610 Review)	0910-AF74

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
359	Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P) (Section 610 Review)	0938-AG81
360	Revisions to HIPAA Code Sets (CMS-0013-P)	0938-AN25
361	Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-P)	0938-AO53
362	Prospective Payment System for Long-Term Care Hospitals RY 2009: Annual Payment Rate Updates (CMS-1393-P)	0938-AO94
363	Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P)	0938-AP01
364	Hospice Wage Index for FY 2009 (CMS-1548-P)	0938-AP14
365	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2009 Rates (CMS-1390-P)	0938-AP15
366	Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2009 (CMS-1404-P) (Reg Plan Seq No. 50)	0938-AP17

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

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
367	End Stage Renal Disease (ESRD) Conditions for Coverage (CMS-3818-F) (Section 610 Review) (Reg Plan Seq No. 52)	0938-AG82
368	Hospice Care Conditions of Participation (CMS-3844-F) (Section 610 Review) (Reg Plan Seq No. 53)	0938-AH27

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

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
369	Hospital Conditions of Participation: Laboratory Services (CMS-3014-F) (Section 610 Review)	0938-AJ29

HHS

Centers for Medicare & Medicaid Services—Long-Term Actions (Continued)

Sequence Number	Title	Regulation Identifier Number
370	Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) (CMS-6006-F)	0938-AO84
371	Medicaid Graduate Medical Education (CMS-2279-F) (Section 610 Review)	0938-AO95

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
372	Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (CMS-1810-F)	0938-AK67
373	Competitive Acquisition for Certain Durable Medical Equipment (DME), Prosthetics, Orthotics, and Supplies (CMS-1270-F)	0938-AN14
374	Medicare Part B Competitive Acquisition of Outpatient Drugs and Biologicals (CMS-1325-F)	0938-AN58
375	Medicaid Prescription Drugs—Average Manufacturer Price (CMS-2238-FC)	0938-AO20
376	Prospective Payment System for Long-Term Care Hospitals RY 2008: Annual Payment Rate Updates and Policy Changes (CMS-1529-F)	0938-AO30
377	Home Health Prospective Payment System Refinements and Rate Update for Calendar Year 2008 (CMS-1541-F)	0938-AO32
378	Cost Limits for Governmentally Operated Providers (CMS-2258-FC) (Completion of a Section 610 Review)	0938-AO57
379	Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2008 (CMS-1551-F)	0938-AO63
380	Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2008 (CMS-1545-F)	0938-AO64
381	Changes to the Hospital Inpatient Prospective Payment Systems and FY 2008 Rates (CMS-1533-FC)	0938-AO70
382	Hospice Wage Index for FY 2008 (CMS-1539-F)	0938-AO72
383	Revised Payment System for Services Furnished in Ambulatory Surgical Centers (ASCs) Effective January 1, 2008 (CMS-1517-F)	0938-AO73
384	Fee Schedule for Payment of Ambulance Services—Update for CY 2008 (CMS-1552-N)	0938-AO85

Department of Health and Human Services (HHS)

Proposed Rule Stage

Substance Abuse and Mental Health Services Administration (SAMHSA)

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

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

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management

practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Paolo Del Vecchio, Department of Health and Human

Services, Substance Abuse and Mental Health Services Administration, Room 13-103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 443-2619

RIN: 0930-AA10

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

Final Rule Stage

**312. CONTROL OF COMMUNICABLE
DISEASES, INTERSTATE AND
FOREIGN QUARANTINE**

Regulatory Plan: This entry is Seq. No. 37 in part II of this issue of the **Federal Register**.

RIN: 0920-AA12

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

Prerule Stage

**313. STATUS OF CERTAIN
ADDITIONAL OVER-THE-COUNTER
DRUG CATEGORY II AND III ACTIVE
INGREDIENTS (SECTION 610 REVIEW)**

Legal Authority: 5 USC 610

Abstract: Section 310.545 (21 CFR part 310.545) codifies a final rule that was issued stating certain first aid antiseptic, vaginal contraceptive, and antimicrobial diaper rash ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective and are misbranded. This rule took into consideration the reports and recommendations of various OTC drug advisory review panels and public comment on proposed Agency regulations. Based on the absence of substantive comments in opposition to the Agency's proposed nonmonograph status for various ingredients, as well as the failure of interested parties to submit new data or information to FDA, the Agency determined that the presence of the subject ingredients in an OTC drug product would result in that product not being generally recognized as safe and effective and would result in misbranding.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 310.545. The purpose of this review is to determine whether the regulation in section 310.545 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 310.545; (2) the nature of the complaints or comments received concerning the regulation in section 310.545; (3) the complexity of the regulations in section 310.545; (4) the extent to which the

regulation in section 310.545 overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the regulation in section 310.545.

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

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	12/01/06	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF75

**314. MEDICAL DEVICES:
CLASSIFICATION/
RECLASSIFICATION; RESTRICTED
DEVICES; ANALYTE SPECIFIC
REAGENTS (SECTION 610 REVIEW)**

Legal Authority: 21 USC 351; 21 USC 352; 21 USC 360j

Abstract: FDA is initiating a review under section 610 of the Regulatory Flexibility Act for two regulations in part 809. The purpose of this review is to determine if 21 CFR part 809.10 and 809.30 should be continued without change, or should be amended or rescinded to minimize adverse economic impact on small entities. FDA is soliciting and will consider comments on the following: 1) The continued need for 21 CFR part 809.10 and 809.30; 2) the nature of complaints or comments received concerning 21 CFR part 809.10 and 809.30; 3) the complexity of 21 CFR part 809.10 and 809.30; 4) the extent to which 21 CFR part 809.10 and 809.30 overlap, duplicate, or conflict with other Federal, State, or local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR part 809.10 and 809.30.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	04/01/07	
End Review	11/00/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
Phone: 240 276-2347
Fax: 240 276-2352
Email: myrna.hanna@fda.hhs.gov

RIN: 0910-AF76

HHS—FDA

Prerule Stage

315. AMENDED ECONOMIC IMPACT ANALYSIS OF FINAL RULE ON USER LABELING ON NATURAL RUBBER-CONTAINING MEDICAL DEVICE (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 357; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374

Abstract: FDA is initiating a review of the regulations in part 801 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine, consistent with stated objectives and applicable statutes, whether the regulations in part 801 should be continued without change, amended, or rescinded in order to minimize any significant economic impact on a substantial number of small entities. FDA will consider and is soliciting comments on the following: 1) The continued need for the regulation; 2) the nature of complaints or comments received concerning the regulation; 3) the complexity of the regulation; 4) the extent to which a regulation in part 801 overlaps, duplicates, or conflicts with other Federal rules, and to the extent feasible, with State and local government rules; and 5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Timetable:

Action	Date	FR Cite
Final Action	09/30/97	62 FR 51021
Final Action Effective	09/30/98	
Begin Review of Current Regulation	01/02/07	
End Review of Current Regulation	12/00/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850
Phone: 240 276-2347
Fax: 240 276-2352
Email: myrna.hanna@fda.hhs.gov

RIN: 0910-AF77

316. FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360j; 21 USC 371; 21 USC 372; 21 USC 373; 21 USC 374; 21 USC 375; 21 USC 376; 21 USC 379; 42 USC 262

Abstract: FDA is undertaking a review of 21 CFR part 54, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in part 54 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulations in part 54; (2) the nature of complaints or comments received concerning the regulations in part 54; (3) the complexity of the regulations in part 54, (4) the extent to which the regulations in part 54 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in part 54.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	12/01/06	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Howard P. Muller, Office of Regulatory Policy, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD-7), 5515 Security Lane, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: howard.mullerjr@fda.hhs.gov

Stephen M. Ripley, Team Leader, Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Suite 200N (HFM-17), 1401 Rockville Pike, Rockville, MD 20852-1448
Phone: 301 827-6210
Fax: 301 827-9434

Elisa D. Harvey, Director, Office of Device Evaluation, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Corp Room 130F (HFZ-215), 1350 Piccard Drive, Rockville, MD 20850
Phone: 301 594-1190
Fax: 301 594-3076
Email: elisa.harvey@fda.hhs.gov

RIN: 0910-AF79

317. BEVERAGES: BOTTLED WATER (SECTION 610 REVIEW)

Legal Authority: 21 USC 321; 21 USC 341; 21 USC 343; 21 USC 343-1; 21 USC 348; 21 USC 349; 21 USC 371; 21 USC 379e

Abstract: Section 165.110 (21 CFR part 165.110) describes requirements for identity and quality standards for bottled water. FDA is undertaking a review of section 165.110 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in section 165.110 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in section 165.110; (2) the nature of complaints or comments received concerning the regulations in section 165.110; (3) the complexity of the regulations; (4) the extent to which the regulations in section 165.110 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in section 165.110.

Timetable:

Action	Date	FR Cite
Begin Review	03/01/07	
End Review	12/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORP (HFS-020),

HHS—FDA

Prerule Stage

5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436-1825

Fax: 301 436-2505

Email: david.zorn@fda.hhs.gov

RIN: 0910-AF80

318. FOOD LABELING; NUTRIENT CONTENT CLAIMS: DEFINITION FOR "HIGH POTENCY" AND DEFINITION OF "ANTIOXIDANT" FOR USE IN NUTRIENT CONTENT CLAIMS FOR DIETARY SUPPLEMENTS AND CONVENTIONAL FOODS (SECTION 610 REVIEW)

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

Abstract: Section 101.54 (21 CFR part 101.54) describes the requirements for when the terms "high potency" and "antioxidant" may be used on the label or in the labeling of foods, including dietary supplements. Section 101.60 (21

CFR part 101.60) describes the requirements for when the terms "low calorie" or "reduced calorie" may be used on the label or in the labeling of such foods. FDA is undertaking a review of sections 101.54 and 101.60 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in sections 101.54 and 101.60; (2) the nature of complaints or comments received concerning the regulations; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.54 and 101.60 overlap, duplicate, or conflict with other Federal

rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.54 and 101.60.

Timetable:

Action	Date	FR Cite
Begin Review	12/01/06	
End Review	11/00/07	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORP (HFS-020), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436-1825

Fax: 301 436-2505

Email: david.zorn@fda.hhs.gov

RIN: 0910-AF83

Department of Health and Human Services (HHS)

Proposed Rule Stage

Food and Drug Administration (FDA)

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

Regulatory Plan: This entry is Seq. No. 38 in part II of this issue of the **Federal Register**.

RIN: 0910-AC52

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 will address external analgesic drug products.

Timetable:

Action	Date	FR Cite
NPRM	12/00/08	
Final Action	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF35

322. OVER-THE-COUNTER (OTC) DRUG REVIEW—INTERNAL ANALGESIC PRODUCTS

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

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

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

Regulatory Plan: This entry is Seq. No. 39 in part II of this issue of the **Federal Register**.

RIN: 0910-AF11

321. OVER-THE-COUNTER (OTC) DRUG REVIEW—EXTERNAL ANALGESIC PRODUCTS

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not

HHS—FDA

Proposed Rule Stage

internal analgesics. The fifth document finalizes the document regarding the required warnings and other labeling. The last document finalizes the Internal Analgesic Products monograph.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/06	71 FR 77314
NPRM Comment Period End	05/25/07	
NPRM (Amendment) (Overindulgence/ Hangover)	06/00/08	
NPRM (Amendment) (Pediatric)	12/00/08	
NPRM (Amendment) (Combinations with Sodium Bicarbonate)	06/00/08	
NPRM (Amendment) (Miscellaneous Issues)	12/00/08	
Final Action (Required Warnings and Other Labeling)	06/00/08	
Final Action (Internal Analgesics)	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF36

323. OVER-THE-COUNTER (OTC) DRUG REVIEW—ORAL HEALTH CARE PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
ANPRM (Plaque Gingivitis)	05/29/03	68 FR 32232
NPRM (Plaque Gingivitis)	12/00/08	
Final Action	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF40

324. OVER-THE-COUNTER (OTC) DRUG REVIEW—SUNSCREEN PRODUCTS

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 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. One action addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection, and the other action addresses combination products containing sunscreen and insect repellent ingredients.

Timetable:

Action	Date	FR Cite
ANPRM (Sunscreen and Insect Repellent)	02/22/07	72 FR 7941
ANPRM Comment Period End	05/23/07	
NPRM (UVA/UVB)	08/27/07	72 FR 49070
NPRM (Sunscreen and Insect Repellent)	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project

Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF43

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

Regulatory Plan: This entry is Seq. No. 40 in part II of this issue of the **Federal Register**.

RIN: 0910-AF61

326. OVER-THE-COUNTER (OTC) DRUG REVIEW—POISON TREATMENT DRUG PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM (IPECAC)	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF68

327. OVER-THE-COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

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

HHS—FDA

Proposed Rule Stage

21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 371a

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

Timetable:

Action	Date	FR Cite
NPRM (Food Handlers)	12/00/08	
NPRM (Testing)	06/00/08	
Final Action (Healthcare)	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF69

328. OVER-THE-COUNTER (OTC) DRUG REVIEW—URINARY ANALGESIC DRUG PRODUCTS

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC

drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	12/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF70

Department of Health and Human Services (HHS)

Final Rule Stage

Food and Drug Administration (FDA)

329. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

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

Abstract: These regulations are one component of the Secretary's initiative to reduce medical errors. The final rule would amend the expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406

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

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD-7), 5515 Security Lane, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AA97

330. CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY INGREDIENTS AND DIETARY SUPPLEMENTS

Regulatory Plan: This entry is Seq. No. 43 in part II of this issue of the **Federal Register**.

RIN: 0910-AB88

331. PREVENTION OF SALMONELLA ENTERITIDIS IN SHELL EGGS

Regulatory Plan: This entry is Seq. No. 44 in part II of this issue of the **Federal Register**.

RIN: 0910-AC14

332. TOLL-FREE NUMBER FOR REPORTING ADVERSE EVENTS ON LABELING FOR HUMAN DRUGS

Legal Authority: 21 USC 355b

Abstract: To require the labeling of human drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act to include a toll-free number for reports of adverse events, and a statement that the number is to be used for reporting purposes only and not to receive medical advice.

HHS—FDA

Final Rule Stage

Timetable:

Action	Date	FR Cite
NPRM	04/22/04	69 FR 21778
NPRM Comment Period End	07/21/04	
Final Action	01/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Carol Drew, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD-7), 5515 Security Lane, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562

RIN: 0910-AC35**333. POSITRON EMISSION TOMOGRAPHY DRUGS; CURRENT GOOD MANUFACTURING PRACTICES****Legal Authority:** PL 105-115, sec 121

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

Timetable:

Action	Date	FR Cite
NPRM	09/20/05	70 FR 55038
NPRM Comment Period End	12/19/05	
Final Action	04/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Brian L. Pendleton, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101 (HFD-7), 5515 Security Lane, Rockville, MD 20852
Phone: 301 594-2041
Fax: 301 827-5562
Email: brian.pendleton@fda.hhs.gov

RIN: 0910-AC55**334. COCHINEAL EXTRACT AND CARMINE LABEL DECLARATION****Legal Authority:** 21 USC 379e(b)

Abstract: The Agency published a proposed rule on January 30, 2006, to

require the label declaration of all foods and cosmetics containing the color additives cochineal extract and carmine in order to protect consumers with allergies to these additives. This proposal was issued in response to adverse event reports received by FDA and to a citizen petition submitted to FDA. The comment period ended on May 1, 2006. FDA intends to issue a final rule after reviewing comments.

Timetable:

Action	Date	FR Cite
NPRM	01/30/06	71 FR 4839
NPRM Comment Period End	05/01/06	
Final Action	05/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Mical E. Honigfort, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, HFS-265, 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436-1278
Fax: 301 436-2972
Email: mical.honigfort@fda.hhs.gov

RIN: 0910-AF12**335. CHARGING FOR INVESTIGATIONAL DRUGS****Legal Authority:** 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 371; 42 USC 262

Abstract: On December 14, 2006, (71 FR 75168), FDA published a proposed rule to amend FDA's investigational new drug regulation concerning charging for investigational drugs. The rule will clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, set forth criteria for charging for an investigational drug for the different types of treatment uses described in the Agency's rule on expanded access to investigational drugs for treatment use, and clarify what costs can be recovered for an investigational drug. The rule is intended to permit charging for a broader range of investigational uses than is explicitly permitted in current regulations.

Timetable:

Action	Date	FR Cite
NPRM	12/14/06	71 FR 75168
NPRM Comment Period End	03/14/07	
Final Action	09/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101, 5515 Security Lane, Rockville, MD 20852

Phone: 301 594-2041

Fax: 301 827-5562

Email: christine.rogers@fda.hhs.gov

RIN: 0910-AF13**336. EXPANDED ACCESS TO INVESTIGATIONAL DRUGS FOR TREATMENT USE**

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

RIN: 0910-AF14**337. OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Common Cold)	12/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF31

HHS—FDA

Final Rule Stage

338. OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (BRONCHODILATOR) PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment— Ephedrine Single Ingredient)	07/13/05	70 FR 40237
Final Action (Technical Amendment)	03/19/07	72 FR 12370
Final Action (Amendment— Ephedrine Single Ingredient)	06/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF32**339. OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (COMBINATION) PRODUCTS**

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360a; 21 USC 371; 21 USC 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 technical amendment revises a paragraph designation in the

CFR. The other action finalizes cough/cold combination products containing oral bronchodilators and expectorants.

Timetable:

Action	Date	FR Cite
NPRM (Amendment) Final Action (Technical Amendment)	07/13/05	70 FR 40232
Final Action	12/00/07	
	06/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF33**340. OVER-THE-COUNTER (OTC) DRUG REVIEW—COUGH/COLD (NASAL DECONGESTANT) PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/04	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/04	69 FR 63482
NPRM (Phenyl propanolamine)	12/22/05	70 FR 75988
Final Action (Amendment) (Sinusitis Claim)	10/31/05	70 FR 58974
Final Action (Phenylephrine Bitartrate)	08/01/06	71 FR 83358
Final Action (Phenyl propanolamine)	12/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF34**341. OVER-THE-COUNTER (OTC) DRUG REVIEW—LABELING OF DRUG PRODUCTS FOR OTC HUMAN USE**

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

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

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/06	71 FR 74474
Final Action	12/00/08	

Regulatory Flexibility Analysis**Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF37**342. OVER-THE-COUNTER (OTC) DRUG REVIEW—LAXATIVE DRUG PRODUCTS**

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

HHS—FDA

Final Rule Stage

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action will address laxative drug products. The other action will address psyllium laxative drug products in a granular dosage form.

Timetable:

Action	Date	FR Cite
Final Action (Granular Psyllium)	03/29/07	72 FR 14669
Final Action (Laxative Drug Products)	06/00/08	
NPRM (Professional Labeling)	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF38

343. OVER-THE-COUNTER (OTC) DRUG REVIEW—SKIN PROTECTANT PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	12/00/07	
Final Action (Fever Blisters/Cold Sores)	12/00/08	
Final Action (Diaper Rash)	12/00/08	
Final Action (Aluminum Acetate) (Technical Amendment)	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF42

344. OVER-THE-COUNTER (OTC) DRUG REVIEW—VAGINAL CONTRACEPTIVE PRODUCTS

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action will address labeling warning statements for products containing Nonoxynol 9. The other action addresses vaginal contraceptive drug products.

Timetable:

Action	Date	FR Cite
NPRM (Vaginal Contraceptive Drug Products)	06/00/08	
Final Action (Warnings)	12/00/07	

Regulatory Flexibility Analysis
Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF44

345. OVER-THE-COUNTER (OTC) DRUG REVIEW—WEIGHT CONTROL PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM (Phenyl propanolamine)	12/22/05	70 FR 75988
NPRM (Benzocaine)	12/00/08	
Final Action (Phenyl propanolamine)	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF45

346. SUBSTANCES PROHIBITED FROM USE IN ANIMAL FOOD OR FEED TO PREVENT THE TRANSMISSION OF BOVINE SPONGIFORM ENCEPHALOPATHY

Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

HHS—FDA

Final Rule Stage

Abstract: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to help strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking.

Timetable:

Action	Date	FR Cite
ANPRM	07/14/04	69 FR 42288
ANPRM Comment Period End	08/13/04	
NPRM	10/06/05	70 FR 58569
NPRM Comment Period End	12/20/05	
Final Action	03/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Burt Pritchett, Biologist, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, HFV-222, 7519 Standish Place, MPN-4, Rockville, MD 20855
Phone: 240 453-6860
Fax: 240 453-6882
Email: burt.pritchett@fda.hhs.gov

RIN: 0910-AF46

347. OVER-THE-COUNTER (OTC) DRUG REVIEW—ANTACID PRODUCTS

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

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Timetable:

Action	Date	FR Cite
Final Action (Sodium Bicarbonate Labeling)	06/00/08	
Final Action (Overindulgence Labeling)	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF52

348. OVER-THE-COUNTER (OTC) DRUG REVIEW—SKIN BLEACHING PRODUCTS

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

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

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51146
NPRM Comment Period End	12/27/06	
Final Action	12/00/08	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF53

**Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)****Long-Term Actions****349. REQUIREMENTS FOR SUBMISSION OF IN VIVO BIOEQUIVALENCE DATA**

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 355a; 21 USC 356; 21 USC 356a to 356c; 21 USC 371; 21 USC 374; 21 USC 379

Abstract: The Food and Drug Administration (FDA) published a proposed regulation on October 29, 2003 (68 FR 61640), that would amend its regulations on submission of bioequivalence (BE) data to require an abbreviated new drug application

(ANDA) applicant to submit data from all BE studies the applicant conducts on a drug product formulation submitted for approval. In the past, ANDA applicants have submitted BE studies demonstrating that a generic product meets BE criteria for FDA to approve the ANDA but have not typically submitted additional BE studies conducted on the same drug product formulation. If finalized, this rule would require ANDA applicants to submit information, in either a complete or summary report, from all additional passing and nonpassing BE studies conducted on the same drug

product formulation submitted for approval.

Timetable:

Action	Date	FR Cite
NPRM	10/29/03	68 FR 61640
Final Action	To Be	Determined

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Christine F. Rogers, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Suite 1101,

HHS—FDA

Long-Term Actions

5515 Security Lane, Rockville, MD
20857

Phone: 301 594-2041

Fax: 301 827-5562

RIN: 0910-AC23

350. HEALTH CLAIMS

Legal Authority: 21 USC 343; 21 USC 371

Abstract: On November 25, 2003 (68 FR 66040), FDA issued an advance notice of proposed rulemaking (ANPRM) to request comments on alternatives for regulating qualified health claims in the labeling of conventional human foods and dietary supplements. FDA also solicited comments on various other issues related to health claims and on the appropriateness and nature of dietary guidance statements on conventional food and dietary supplement labels. This ANPRM was signaled in the July 11, 2003 (68 FR 41387), notice that announced the availability of the final report of the FDA Task Force on the Consumer Health Information for Better Nutrition Initiative.

Comments on the regulatory alternatives and additional topics identified in the ANPRM will inform FDA decisions about regulation of qualified health claims.

Timetable:

Action	Date	FR Cite
ANPRM	11/25/03	68 FR 66040
ANPRM Comment Period Extended	01/27/04	69 FR 3868
ANPRM Comment Period End	02/25/04	
NPRM	To Be	Determined

**Regulatory Flexibility Analysis
Required:** Yes

Agency Contact: Julie Moss, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-830), 5100 Paint Branch Parkway, College Park, MD 20740

Phone: 301 436-2373

Fax: 301 436-2639

Email: julie.moss@fda.hhs.gov

RIN: 0910-AF09

**351. OVER-THE-COUNTER (OTC)
DRUG REVIEW—OPHTHALMIC
PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Emergency First Aid Eyewashes)	12/00/08	

**Regulatory Flexibility Analysis
Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF39

**352. OVER-THE-COUNTER (OTC)
DRUG REVIEW—OVERINDULGENCE
IN FOOD AND DRINK PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) Final Action	01/05/05 12/00/08	70 FR 741

**Regulatory Flexibility Analysis
Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF51

**353. OVER-THE-COUNTER (OTC)
DRUG REVIEW—STIMULANT DRUG
PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	12/00/08	

**Regulatory Flexibility Analysis
Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF56

HHS—FDA

Long-Term Actions

**354. OVER-THE-COUNTER
ANTIDIARRHEAL DRUG PRODUCTS**

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

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

Timetable:

Action	Date	FR Cite
NPRM	12/00/08	

**Regulatory Flexibility Analysis
Required:** Yes

Agency Contact: Walter Jefferson Ellenberg, Regulatory Project Management Officer, Center for Drug Evaluation and Research, Department of Health and Human Services, Food and Drug Administration, HFD-560, 5600 Fishers Lane, Rockville, MD 20857
Phone: 301 796-0885
Fax: 301 796-9899

Email: walter.ellenberg@fda.hhs.gov
RIN: 0910-AF63

**355. FOOD LABELING; SERVING
SIZES; REFERENCE AMOUNT FOR
BAKING POWDER, BAKING SODA,
AND PECTIN (SECTION 610 REVIEW)**

Legal Authority: 15 USC 1453; 15 USC 1454; 15 USC 1455; 21 USC 321; 21 USC 331; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371

Abstract: Section 101.9 (21 CFR part 101.9) describes the nutrition labeling regulations for the reference amount customarily consumed per eating occasion for the food category "Baking powder, baking soda, pectin." Section 101.12 (21 CFR part 101.12) includes 1/8 teaspoon (tsp) as an additional allowable household measure. FDA is undertaking a review of sections 101.9 and 101.12 under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.9 and 101.12 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need

for the regulations in sections 101.9 and 101.12; (2) the nature of complaints or comments received concerning the regulations in sections 101.9 and 101.12; (3) the complexity of the regulations; (4) the extent to which the regulations in sections 101.9 and 101.12 overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in sections 101.9 and 101.12.

Timetable:

Action	Date	FR Cite
Begin Review	12/00/08	
End Review	03/00/09	

**Regulatory Flexibility Analysis
Required:** Undetermined

Agency Contact: David Zorn, Lead Economist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, ORP (HFS-020), 5100 Paint Branch Parkway, College Park, MD 20740
Phone: 301 436-1825
Fax: 301 436-2505
Email: david.zorn@fda.hhs.gov

RIN: 0910-AF99

**Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)****Completed Actions****356. MEDICAL DEVICES; CURRENT
GOOD MANUFACTURING PRACTICE
(CGMP) FINAL RULE; QUALITY
SYSTEMS REGULATIONS
(COMPLETION OF A SECTION 610
REVIEW)**

Legal Authority: 5 USC 610

Abstract: FDA has undertaken a review of part 820 under section 610 of the Regulatory Flexibility Act. The agency did not receive any comments during the review process of part 820 under section 610 review, therefore the regulation will continue without change. The purpose of the review was to determine whether the regulations in part 820 should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on substantial number of small entities.

FDA has solicited comments on, the following (1) the continued need for the regulation in part 820; (2) the nature of complaints or comments received concerning the regulation in part 820; (3) the complexity of the regulation in part 820; (4) the extent to which the regulation in part 820 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation in part 820.

The section 610 review has been carried out along with a regulation review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency's regulatory

program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order. The combined effect of the two reviews will be to determine if it is possible to redesign current good manufacturing practices in ways that will maintain or increase the effectiveness of preventive and sanitary controls, and, at the same time, reduce compliance and other costs associated with the regulations.

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	01/05/06	
End Review	07/31/07	

**Regulatory Flexibility Analysis
Required:** No

HHS—FDA

Completed Actions

Agency Contact: Myrna Hanna, Regulations Staff, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health (HFZ-215), PI50 RM150F, 1350 Piccard Drive, Rockville, MD 20850

Phone: 240 276-2347

Fax: 240 276-2352

Email: myrna.hanna@fda.hhs.gov

RIN: 0910-AF71

357. PACKAGE SIZE LIMITATION FOR SODIUM PHOSPHATES ORAL SOLUTION AND WARNING AND DIRECTION STATEMENTS FOR ORAL AND RECTAL SODIUM PHOSPHATES FOR OVER-THE-COUNTER LAXATIVE USE (SECTION 610 REVIEW)

Legal Authority: 5 USC 610

Abstract: Section 201.307 (21 CFR sec. 201.307) describes a final rule to limit the container size for sodium phosphates oral solution (dibasic sodium phosphate/monobasic sodium phosphate oral solution) to not greater than 90 milliliters (mL) (3 ounces (oz)) when used as an over-the-counter (OTC) laxative drug product. FDA limited the container size due to reports of deaths associated with an overdose of sodium phosphates when packaged in a larger size container and a larger-than-intended dose was ingested inadvertently. In addition, this final rule required warning and direction statements to inform consumers that exceeding the recommended dose of oral and rectal sodium phosphates products in a 24-hour period could be harmful.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.307. The purpose of this review is to determine whether the regulation in section 201.307 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in section 201.307; (2) the nature of the complaints or comments received concerning the regulation in section 201.307; (3) the complexity of the regulation in section 201.307; (4) the extent to which the regulation in section 201.307 overlaps,

duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the package size and labeling regulation in section 201.307.

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

Completed:

Reason	Date	FR Cite
End Review	09/04/07	

Regulatory Flexibility Analysis Required: No

Agency Contact: Walter Jefferson Ellenberg
Phone: 301 796-0885
Fax: 301 796-9899
Email: walter.ellenberg@fda.hhs.gov

RIN: 0910-AF73

358. OVER-THE-COUNTER DRUG PRODUCTS CONTAINING ANALGESIC/ANTIPYRETIC ACTIVE INGREDIENTS FOR INTERNAL USE: REQUIRED ALCOHOL WARNING (SECTION 610 REVIEW)

Legal Authority: 5 USC 610

Abstract: Section 201.322 describes a regulation that requires an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. FDA issued the final rule after considering comments on the Agency's proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products: A proposed regulation to establish an alcohol warning, recommendations

from its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC), and data submitted to the agency.

FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in section 201.322. The purpose of this review is to determine whether the regulation in section 201.322 should be continued without change, or whether it should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA proposed to remove section 201.322 in the Federal Register on December 26, 2006 (71 FR 77314). FDA will consider the comments received in response to that proposal and, in addition, is soliciting comments on the following: (1) The continued need for the regulation in section 201.322; (2) the nature of the complaints or comments received concerning the regulation in section 201.322; (3) the complexity of the regulation in section 201.322; (4) the extent to which the regulation in section 201.322 overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling regulation in section 201.322.

The section 610 review has been carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the Agency's regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order. This review concluded with the publication of proposed amendment of the tentative final monograph; required warnings and other labeling. 71 FR 77314

Completed:

Reason	Date	FR Cite
End Review	12/26/06	

Regulatory Flexibility Analysis Required: No

Agency Contact: Walter Jefferson Ellenberg

HHS—FDA

Completed Actions

Phone: 301 796-0885
Fax: 301 796-9899

Email: walter.ellenberg@fda.hhs.gov
RIN: 0910-AF74

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

Proposed Rule Stage

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

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

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

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	02/00/08	

Regulatory Flexibility Analysis Required: No

Agency Contact: Commander Mercedes Benitez-McCrary, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3-05-14, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-5716
Email: mercedes.benitezmcrcary@cms.hhs.gov

Lynn M. Riley, Clinical Standards Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1286
Email: lynn.riley@cms.hhs.gov

RIN: 0938-AG81

360. REVISIONS TO HIPAA CODE SETS (CMS-0013-P)

Legal Authority: PL 104-191

Abstract: This proposed rule would revise some of the adopted transaction and code set standards detailed in regulations published by HHS on August 17, 2000, and February 20, 2003.

Timetable:

Action	Date	FR Cite
NPRM	01/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Denise Buening, Health Insurance Specialist, Office of E-Health Standards and Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop S2-26-17, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-6711
Email: denise.buening@cms.hhs.gov

RIN: 0938-AN25

361. HOME AND COMMUNITY-BASED SERVICES (HCBS) STATE PLAN OPTION (CMS-2249-P)

Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6086

Abstract: This proposed rule would amend the Medicaid regulations to define and describe the home and community-based State plan services implementing new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

Timetable:

Action	Date	FR Cite
NPRM	03/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Theresa Pratt, Director, Division of Integrated Health Systems, Disabled and Elderly Health Programs Group, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center

for Medicaid State Operations, Mailstop S2-14-26, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9499
Email: theresa.pratt@cms.hhs.gov

RIN: 0938-AO53

362. PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS RY 2009: ANNUAL PAYMENT RATE UPDATES (CMS-1393-P)

Legal Authority: sec 123 PL 106-113; sec 307(b) PL 106-554

Abstract: This major rule proposes changes to the Medicare long-term care hospitals (LTCH) prospective payment system (PPS) annual updates the payment rates for rate year (RY) 2009.

Timetable:

Action	Date	FR Cite
NPRM	01/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Judith Richter, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C4-16-07, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-2590
Email: judith.richter@cms.hhs.gov

RIN: 0938-AO94

363. • ESTABLISHING ADDITIONAL MEDICARE PROVIDER AND SUPPLIER ENROLLMENT SAFEGUARDS (CMS-6045-P)

Legal Authority: sec. 4312(a) of BBA of 1997

Abstract: This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges.

Timetable:

Action	Date	FR Cite
NPRM	02/00/08	

Regulatory Flexibility Analysis Required: Yes

HHS—CMS

Proposed Rule Stage

Agency Contact: James Bossenmeyer, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mailstop C3-02-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9317
Email: james.bossenmeyer@cms.hhs.gov

RIN: 0938-AP01

364. ● HOSPICE WAGE INDEX FOR FY 2009 (CMS-1548-P)

Legal Authority: 42 USC 1814(i)(1) and 1814(i)(2)

Abstract: This rule proposes the annual update to the hospice wage index for FY 2009. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Timetable:

Action	Date	FR Cite
NPRM	04/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Terri Deutsch, Technical Advisor, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C5-08-18, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9462
Email: terri.deutsch@cms.hhs.gov

RIN: 0938-AP14

365. ● CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2009 RATES (CMS-1390-P)

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

Abstract: This major rule proposes to revise the Medicare hospital Inpatient Prospective Payment Systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. Under section 106(b)(2) of the Tax Relief and Health Care Act of 2006, this rule also proposes to revise the wage index adjustment under the hospital IPPS.

Timetable:

Action	Date	FR Cite
NPRM	04/00/08	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Marc Hartstein, Deputy Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Mail Stop C4-25-11, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-4548
Email: marc.hartstein@cms.hhs.gov

RIN: 0938-AP15

366. ● CHANGES TO THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM FOR CY 2009 (CMS-1404-P)

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

RIN: 0938-AP17

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

Final Rule Stage

367. END STAGE RENAL DISEASE (ESRD) CONDITIONS FOR COVERAGE (CMS-3818-F) (SECTION 610 REVIEW)

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

RIN: 0938-AG82

368. HOSPICE CARE CONDITIONS OF PARTICIPATION (CMS-3844-F) (SECTION 610 REVIEW)

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

RIN: 0938-AH27

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

Long-Term Actions

369. HOSPITAL CONDITIONS OF PARTICIPATION: LABORATORY SERVICES (CMS-3014-F) (SECTION 610 REVIEW)

Legal Authority: 42 USC 1302; 42 USC 1395hh

Abstract: This rule requires hospitals that transfuse blood and blood components to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospital received and transfused are at increased

risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and maintain records for at least 10 years.

Timetable:

Action	Date	FR Cite
NPRM	11/16/00	65 FR 69416
Interim Final Rule	08/24/07	72 FR 48562

Action	Date	FR Cite
Interim Final Rule Comment Period End	10/23/07	
Final Action	08/00/10	

Regulatory Flexibility Analysis Required: No

Agency Contact: Mary Collins, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Clinical Standards Group, Mailstop S3-02-01,

HHS—CMS

Long-Term Actions

7500 Security Boulevard, Baltimore, MD 21244

Phone: 410 786-3189

Email: mary.collins@cms.hhs.gov

RIN: 0938-AJ29

370. SURETY BOND REQUIREMENT FOR SUPPLIERS OF DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) (CMS-6006-F)

Legal Authority: sec 4312(a) of BBA of 1997

Abstract: This rule implements section 4312(a) of the Balanced Budget Act of 1997, which requires a Medicare supplier of durable medical equipment (DME) to furnish CMS with a surety bond.

Timetable:

Action	Date	FR Cite
NPRM	08/01/07	72 FR 42001
NPRM Comment Period End	10/01/07	
Final Action	08/00/10	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Frank Whelan, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Financial Management, Mailstop, C3-02-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-1302
Email: frank.whelan@cms.hhs.gov

RIN: 0938-AO84

371. • MEDICAID GRADUATE MEDICAL EDUCATION (CMS-2279-F) (SECTION 610 REVIEW)

Legal Authority: Title XIX; Social Security Act

Abstract: As part of the President's 2008 Budget, this major rule establishes that States may not include GME as a reimbursable cost or program under their approved Medicaid State Plan. The rule enhances fiscal integrity and improves accountability with respect to

payment for medical services in the Medicaid program.

Timetable:

Action	Date	FR Cite
NPRM	05/23/07	72 FR 28930
NPRM Comment Period End	06/22/07	
Final Action	11/00/08	

Regulatory Flexibility Analysis Required: No

Agency Contact: Dianne Heffron, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Medicaid State Operations, Mailstop, S3-13-15, 7500 Security Boulevard, Baltimore, MD 21224
Phone: 410 786-3247
Fax: 410-786-1008
Email: dianne.heffron@cms.hhs.gov

RIN: 0938-AO95

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

Completed Actions

372. PHYSICIANS' REFERRALS TO HEALTH CARE ENTITIES WITH WHICH THEY HAVE FINANCIAL RELATIONSHIPS (CMS-1810-F)

Legal Authority: 42 USC 1877

Abstract: This final rule is the third phase (Phase III) of a final rulemaking amending our regulations regarding the physician self-referral prohibition in section 1877 of the Social Security Act (the Act). Specifically, this rule finalizes and responds to public comments regarding the Phase II interim final rule with comment period published on March 26, 2004. Phase II set forth the self-referral prohibition and applicable definitions, interpreted various statutory exceptions to the prohibition, and created additional regulatory exceptions for arrangements that do not pose a risk of program or patient abuse (69 FR 16054). In response to public comments in Phase III final rule, we have reduced the regulatory burden on the health care industry through the interpretation of statutory exceptions and by modifying the exceptions that were created using the Secretary's

discretionary authority under section 1877(b)(4) of the Act to promulgate exceptions for financial relationships that pose no risk of program or patient abuse.

Completed:

Reason	Date	FR Cite
Final Action	09/05/07	72 FR 51012

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Joanne Sinsheimer
Phone: 410 786-4620
Email: jsinsheimer@cms.hhs.gov

Lisa Ohrin
Phone: 410 786-4565
Email: lisa.ohrin@cms.hhs.gov

RIN: 0938-AK67

373. COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT (DME), PROSTHETICS, ORTHOTICS, AND SUPPLIES (CMS-1270-F)

Legal Authority: PL 108-173, MMA; Deficit Reduction Act of 2005, PL 109-171, sec 5101

Abstract: Section 302 of the Medicare Modernization Act establishes DME competitive bidding. National competitive bidding will provide a program for using market forces to set Medicare payment amounts. This will create incentives for suppliers to provide quality items and services while at the same time providing Medicare with reasonable prices for payment. This rule also incorporates provisions from section 5105 of the DRA of 2005, which concerns beneficiary ownership of certain DMEs.

Completed:

Reason	Date	FR Cite
Notice	04/10/07	72 FR 16794
Final Action	04/11/07	72 FR 17002

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ralph Goldberg
Phone: 410 786-4870
Email: ralph.goldberg@cms.hhs.gov

RIN: 0938-AN14

HHS—CMS

Completed Actions

**374. MEDICARE PART B
COMPETITIVE ACQUISITION OF
OUTPATIENT DRUGS AND
BIOLOGICALS (CMS-1325-F)**

Legal Authority: MMA of 2003, sec 303(d)

Abstract: Section 303(d) of the Medicare Modernization Act requires the implementation of a competitive bidding program for Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning July 1, 2006, physicians will be given a choice between purchasing these drugs and being paid by Medicare under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process. If the physician elects to obtain drugs from a competitive vendor, the vendor will bill Medicare for the drug.

Completed:

Reason	Date	FR Cite
Withdrawn	08/08/07	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Corinne Axelrod
Phone: 410 786-5620
Email: corinne.axelrod@cms.hhs.gov

RIN: 0938-AN58

**375. MEDICAID PRESCRIPTION
DRUGS—AVERAGE MANUFACTURER
PRICE (CMS-2238-FC)**

Legal Authority: 42 USC 1396r.8; Deficit Reduction Act of 2005, PL 109-171, sec 6001 to 6003

Abstract: This final rule implements sections 6001, 6002, and 6003 of the Deficit Reduction Act of 2005. This rule sets the Federal upper reimbursement limit (FUL) as 250 percent of the average manufacturer price (AMP) for drugs on the FUL list, and will clarify the requirements and manner in which AMPs are determined for multiple-source drugs and other drug payment revisions. This rule also lists the physician administered multiple-source drugs that the Secretary determines have the highest dollar volume of dispensing in Medicaid and will require manufacturers to include authorized generics when they report their AMP and best price for covered outpatient drugs to the Secretary.

Completed:

Reason	Date	FR Cite
Final Action	07/17/07	72 FR 39142

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Yolanda Lashawn Reese
Phone: 410 786-9898
Fax: 410 786-5882
Email: yolanda.reese@cms.hhs.gov

RIN: 0938-AO20

**376. PROSPECTIVE PAYMENT
SYSTEM FOR LONG-TERM CARE
HOSPITALS RY 2008: ANNUAL
PAYMENT RATE UPDATES AND
POLICY CHANGES (CMS-1529-F)**

Legal Authority: PL 106-113, sec 123 ; PL 106-554, sec 307(b)

Abstract: This rule finalizes the annual payment rate update for the Rate Year (RY) 2008 prospective payment system for Medicare long-term care hospitals and also presents proposed changes or revisions on LTCH PPS policy for public comment.

Completed:

Reason	Date	FR Cite
Final Action	05/11/07	72 FR 26870

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Judy Richter
Phone: 410 786-2590
Email: judith.richter@cms.hhs.gov

RIN: 0938-AO30

**377. HOME HEALTH PROSPECTIVE
PAYMENT SYSTEM REFINEMENTS
AND RATE UPDATE FOR CALENDAR
YEAR 2008 (CMS-1541-F)**

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

Abstract: This rule, CMS-1541-F, estimates the net impact, including a 2.75 percent reduction to the case-mix weights to account for nominal increase in case-mix, to be approximately \$20 million in CY 2008 expenditures. That estimate incorporates the 3.0 percent home health market basket increase (an estimated additional \$430 million in CY 2008 expenditures attributable only to the CY 2008 home health market basket update), and the 2.75 percent decrease (-\$410 million for the first year of a 3-year phase in) to the HH

PPS national standardized 60-day episode rate to account for the nominal increase in case-mix under the HH PPS.

Completed:

Reason	Date	FR Cite
NPRM	05/04/07	72 FR 25356
Final Action	08/29/07	72 FR 49761

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Randy L. Thronset
Phone: 410 786-0131
Email: randy.thronset@cms.hhs.gov

RIN: 0938-AO32

**378. COST LIMITS FOR
GOVERNMENTALLY-OPERATED
PROVIDERS (CMS-2258-FC)
(COMPLETION OF A SECTION 610
REVIEW)**

Legal Authority: sec 1102 of the Social Security Act (42 USC 1302)

Abstract: The final rule with comment will: (1) Clarify that only units of government are able to participate in the financing of the non-Federal share; (2) establish minimum requirements for documenting cost when using a certified public expenditure; (3) limit providers operated by units of government to reimbursement that does not exceed the cost of providing covered services to eligible Medicaid recipients; and (4) establish a new regulatory provision explicitly requiring that providers receive and retain the total computable amount of their Medicaid payments.

Timetable:

Action	Date	FR Cite
NPRM	01/18/07	72 FR 2236
NPRM Comment Period End	03/19/07	
Final Action	05/29/07	72 FR 29748

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Aaron Blight, Technical Director, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicaid State Operations, Mailstop S2-01-16, 7500 Security Boulevard, Baltimore, MD 21244
Phone: 410 786-9560
Fax: 410786-1008
Email: aaron.blight@cms.hhs.gov

RIN: 0938-AO57

HHS—CMS

Completed Actions

379. PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT REHABILITATION FACILITIES FOR FY 2008 (CMS-1551-F)

Legal Authority: SSA, sec 1886(i); PL 105-33; PL 106-554; PL 106-113

Abstract: This rule updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2008.

Completed:

Reason	Date	FR Cite
NPRM	05/08/07	72 FR 26230
Final Action	08/07/07	72 FR 44283

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: William Ullman
Phone: 410 786-5667
Email: bill.ullman@cms.hhs.gov

RIN: 0938-AO63

380. PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED BILLING FOR SKILLED NURSING FACILITIES—UPDATE FOR FY 2008 (CMS-1545-F)

Legal Authority: Social Security Act, sec 1888(e)

Abstract: This proposed rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs), for fiscal year (FY) 2008. In addition, this rule revises and rebase the SNF market basket.

Completed:

Reason	Date	FR Cite
NPRM	05/04/07	72 FR 25526
Final Action	08/03/07	72 FR 43412

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: William Ullman
Phone: 410 786-5667
Email: bill.ullman@cms.hhs.gov

RIN: 0938-AO64

381. CHANGES TO THE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEMS AND FY 2008 RATES (CMS-1533-FC)

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

Abstract: This rule proposes to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems.

Completed:

Reason	Date	FR Cite
NPRM	05/03/07	72 FR 24680
Final Action	08/22/07	72 FR 47130

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Marc Hartstein
Phone: 410 786-4548
Email: marc.hartstein@cms.hhs.gov

RIN: 0938-AO70

382. HOSPICE WAGE INDEX FOR FY 2008 (CMS-1539-F)

Legal Authority: 42 USC 1814(i)(1) and 1814(i)(2)

Abstract: This rule updates the hospice wage index for FY 2008. The wage index is used to reflect local differences in wage levels. The hospice wage index methodology and values are based on recommendations of a negotiated rulemaking advisory committee and were originally published on August 8, 1997.

Completed:

Reason	Date	FR Cite
NPRM	05/01/07	72 FR 24116
Final Action	08/31/07	72 FR 50214

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Terri Deutsch
Phone: 410 786-9462
Email: terri.deutsch@cms.hhs.cms

RIN: 0938-AO72

383. REVISED PAYMENT SYSTEM FOR SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS (ASCS) EFFECTIVE JANUARY 1, 2008 (CMS-1517-F)

Legal Authority: 42 USC 1833(i)(2)(D)(iii)

Abstract: This rule revises the method by which Medicare sets payment rates for ASC facility services and includes illustrative new payment rates for ASC services in accordance with that methodology. This rule finalizes policies proposed as part of the August 23, 2006, CY 2007 Outpatient Prospective Payment System rule.

Completed:

Reason	Date	FR Cite
Final Action	08/02/07	72 FR 42470

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Kim Neuman
Phone: 410 786-7802
Email: kim.neuman@cms.hhs.gov

RIN: 0938-AO73

384. FEE SCHEDULE FOR PAYMENT OF AMBULANCE SERVICES—UPDATE FOR CY 2008 (CMS-1552-N)

Legal Authority: sec 1834 (e) of the Social Security Act

Abstract: This notice updates the fee schedule for ambulance services under the Medicare program, implementing section 1834(e) of the Social Security Act (effective January 1, 2008).

Completed:

Reason	Date	FR Cite
Withdrawn	08/08/07	

Regulatory Flexibility Analysis

Required: Yes

Agency Contact: Anne Tayloe
Phone: 410 786-4546
Email: anne.tayloe@cms.hhs.gov

RIN: 0938-AO85

[FR Doc. 07-04897 Filed 12-07-07; 8:45 am]

BILLING CODE 4150-24-S