Action	Date	FR Cite
NPRM Comment Period End	08/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF67

885. OVER–THE–COUNTER (OTC) DRUG REVIEW—TOPICAL ANTIMICROBIAL DRUG PRODUCTS

Priority: Routine and Frequent

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

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358

Legal Deadline: None

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

Timetable:

Action	Date	FR Cite
NPRM (Consumer Products)	12/00/06	
NPRM (Food Handlers)	12/00/06	
NPRM (Healthcare Antiseptics)	12/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Local, State

Federalism: This action may have federalism implications as defined in EO 13132.

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RIN: 0910–AF69

886. • IMPORT TOLERANCES FOR ANIMAL DRUGS

Priority: Substantive, Nonsignificant

Legal Authority: 21 USC 360b(a)(6)

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: FDA plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerances will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the Act) and may be imported into the U.S.

Timetable:

Action	Date	FR Cite
NPRM	12/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No

Government Levels Affected: None

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RIN: 0910–AF78

887. • CURRENT GOOD MANUFACTURING PRACTICE FOR COMBINATION PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

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 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The proposed rule would clarify and streamline the current good manufacturing practice (cGMP) requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a flexible quality management regulatory framework that recognizes that, in most instances, for combination products, a properly implemented quality system program under one set of medical product cGMP regulations will meet the requirements of another set (e.g., application of cGMPs for finished pharmaceuticals in 21 CFR 210/211 will generally meet the requirements of the device quality system regulations in 21 CFR 820). It would allow manufacturers the flexibility to select either the cGMP or quality system regulation to apply for the manufacture of their combination product, provided that their system incorporates select, key provisions from the regulations pertaining to the other part of their combination product. It would avoid the necessity to fully implement both sets of cGMP regulations when manufacturing combination products. The proposed rule is intended to ensure consistency and appropriateness in the regulation of combination products.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

Agency Contact: James S. Cohen, Senior Counsel, Department of Health and Human Services, Food and Drug

HHS—FDA **Proposed Rule Stage**

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RIN: 0910–AF81

888. ● POSTMARKET SAFETY REPORTING FOR COMBINATION PRODUCTS

Priority: Other Significant

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 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

CFR Citation: Not Yet Determined

Legal Deadline: None

Abstract: The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products and specify sponsors' reporting requirements for each type of combination product. The proposed rule would clarify the circumstances in which following one set of postmarket safety reporting regulations generally would meet the requirements of another set, and the circumstances in which these requirements would be supplemented with specific reporting provisions applicable to the other constituent part of the combination product. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/00/07	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

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RIN: 0910–AF82

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

Final Rule Stage

889. SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Priority: Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates: Undetermined

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

CFR Citation: 21 CFR 310; 21 CFR 312; 21 CFR 314; 21 CFR 320; 21 CFR 600; 21 CFR 601; 21 CFR 606

Legal Deadline: None

Abstract: This regulation is 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 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
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period Extension End	10/14/03	
Comment Review End	10/00/06	

Regulatory Flexibility Analysis Required: Yes

Small Entities Affected: Businesses

Government Levels Affected: Undetermined

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RIN: 0910–AA97

890. APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG; COMPLETE RESPONSE LETTER; AMENDMENTS TO UNAPPROVED APPLICATIONS

Priority: Substantive, Nonsignificant. Major status under 5 USC 801 is undetermined.

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

CFR Citation: 21 CFR 312; 21 CFR 314

Legal Deadline: None

Abstract: The rule would amend the regulations on marketing approval of new drugs to discontinue the use of approvable and not approvable letters when taking action on a marketing application and instead use complete response letters. The rule would also amend the regulations on extension of the review clock because of amendments to applications.

Timetable:

Action	Date	FR Cite
NPRM	07/20/04	69 FR 43357
Final Action	10/00/06	

Regulatory Flexibility Analysis Required: No

Small Entities Affected: No