

establish a Class E surface area during those times the ATCT is closed. Controlled airspace extending upward from the surface is needed to contain aircraft executing instrument approach procedures. The area would be depicted on appropriate aeronautical charts. Class D airspace designations are published in paragraph 5000, Class E airspace areas designated as an extension to a Class D surface area are published in paragraph 6004, and Class E airspace areas designated as a surface area for an airport are published in paragraph 6002 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an establishment body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103; 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

##### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation

Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

#### Paragraph 5000 Class D airspace.

\* \* \* \* \*

#### AGL SD D Rapid City, SD [Revised]

Rapid City Regional Airport, SD  
(Lat. 44°02'43"N., long. 103°03'27"W.)  
Ellsworth AFB, SD  
(Lat. 44°08'42"N., long. 103°06'13"W.)

That airspace extending upward from the surface to and including 5,700 feet MSL within a 4.3-mile radius of the Rapid City Regional Airport, SD, excluding the portion north of a line between the intersection of the Rapid City Regional Airport 4.3-mile radius and the Ellsworth AFB, SD, 4.7-mile radius. This Class D airspace area is effective during the specific dates and times established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

\* \* \* \* \*

#### Paragraph 6004 Class E airspace areas designated as an extension to a Class D surface area.

\* \* \* \* \*

#### AGL SD E4 Rapid City, SD [Revised]

Rapid City Regional Airport, SD  
(Lat. 44°02'43"N., long. 103°03'27"W.)  
Ellsworth AFB, SD  
(Lat. 44°08'42"N., long. 103°06'13"W.)  
Rapid City VORTAC  
(Lat. 43°58'34"N., long. 103°00'44"W.)  
Ellsworth AFB TACAN  
(Lat. 44°08'20"N., long. 103°06'06"W.)

That airspace extending upward from the surface within 2.6 miles each side of the Rapid City VORTAC 155°/335° radials extending from the 4.3-mile radius of the Rapid City Regional Airport to 7.0 miles southeast of the VORTAC and within 2.6 miles each side of the Ellsworth AFB TACAN 129° radial, extending from the Ellsworth AFB 4.7-mile radius of the airport to 7.0 miles southeast of the TACAN, excluding that airspace within the Rapid City, SD, Class D airspace area. This Class E airspace area is effective during the specific dates and times established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

\* \* \* \* \*

#### Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

\* \* \* \* \*

#### AGL SD E2 Rapid City, SD [New]

Rapid City Regional Airport, SD  
(Lat. 44°02'43"N., long. 103°03'27"W.)  
Ellsworth AFB, SD  
(Lat. 44°08'42"N., long. 103°06'13"W.)  
Rapid City VORTAC  
(Lat. 43°58'34"N., long. 103°00'44"W.)  
Ellsworth AFB TACAN  
(Lat. 44°08'20"N., long. 103°06'06"W.)

Within an 4.3-mile radius of the Rapid City Regional Airport, SD, excluding the portion

north of a line between the intersection of the Rapid City Regional Airport 4.3-mile radius and the Ellsworth AFB, SD, 4.7-mile radius, and that airspace extending upward from the surface within 2.6 miles each side of the Rapid City VORTAC 155°/335° radials extending from the 4.3-mile radius of the Rapid City Regional Airport to 7.0 miles southeast of the VORTAC and within 2.6 miles each side of the Ellsworth AFB TACAN 129° radial, extending from the Ellsworth AFB 4.7-mile radius of the airport to 7.0 miles southeast of the TACAN, excluding that airspace within the Rapid City, SD, Class D airspace area. This Class E airspace area is effective during the specific dates and times established in advance by Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

\* \* \* \* \*

Issued in Des Plaines, Illinois on December 14, 1998.

**Marueen Woods,**

*Manager, Air Traffic Division.*

[FR Doc. 99–83 Filed 1–4–99; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 2, 3, 5, 10, 12, 16, 20, 25, 50, 54, 56, 58, 60, 70, 71, 200, 201, 202, 206, 207, 210, 211, 299, 300, 310, 312, 314, 316, 320, 333, 369, 510, 514, 520, 522, 524, 529, 800, 801, 807, 809, 812, and 860**

[Docket No. 98N–0720]

### Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Companion Document to Direct Final Rule

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend its regulations to remove references to the repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act), under which the agency certified antibiotic drugs. The agency is also proposing to remove references to the repealed antibiotic monograph regulations and to those regulations dealing with antibiotic applications. The agency is taking this action in accordance with provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

**DATES:** Submit written comments on or before March 22, 1999.

**ADDRESSES:** Submit written comments on the proposed rule to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

For human drugs, Christine F. Rogers or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

For animal drugs, Richard L. Arkin, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0141.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

As described more fully in the related direct final rule, section 125(b) of FDAMA (Pub. L. 105-115) repealed section 507 of the act (21 U.S.C. 357) and made conforming amendments to the act and other provisions of Federal law. Section 507 of the act was the statutory provision under which the agency certified antibiotic drugs. FDA is proposing to make conforming amendments to Title 21 of the Code of Federal Regulations. This proposed rule removes citations to section 507 of the act. It also removes references to: Certification of antibiotics, the antibiotic certification regulations, specific antibiotic monographs, references to antibiotic drug applications, abbreviated antibiotic drug applications, and supplemental antibiotic drug applications.

**II. Additional Information**

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical. This companion proposed rule will provide the procedural framework to finalize the rule in the event the direct final rule receives significant adverse comments and is withdrawn. The comment period for this companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule.

The amendments contained in this proposed rule are a direct result of the repeal of the statutory provision. If no significant adverse comment is received

in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends, and FDA intends the direct final rule to become effective 30 days after publication of the confirmation document. If FDA receives significant adverse comments, the agency will withdraw the direct final rule. FDA will proceed to respond to all of the comments received regarding the rule and, if appropriate, the rule will be finalized under this companion proposed rule using usual notice-and-comment procedures.

For additional information, see the corresponding direct final rule published elsewhere in the final rules section of this issue of the **Federal Register**. If FDA receives significant adverse comments, the agency will withdraw the direct final rule within 30 days after the comment period ends and will treat those comments as comments on this proposed rule. The agency will address the comments in a subsequent final rule. FDA will not provide additional opportunity for comment. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment, unless the comment states why this rule would be ineffective without the additional change.

**III. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

**IV. Analysis of Impacts**

FDA has examined the impact of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule

as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires that if a rule has a significant impact on a substantial number of small entities, the agency must analyze regulatory options to minimize the economic impact on small entities. The agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires an agency to prepare a budgetary impact statement before issuing any rule likely to result in a Federal mandate that may result in expenditures by State, local, and tribal governments or the private sector of \$100 million (adjusted annually for inflation) in any 1 year. These conforming amendments will not result in any increased expenditures by State, local, and tribal governments or the private sector. Because this proposed rule will not result in an expenditure of \$100 million or more on any governmental entity or the private sector, no budgetary impact statement is required.

This proposed rule is intended to make conforming changes to FDA's regulations necessitated by repeal of the section 507 of the act that provided for the certification of antibiotic drugs. Accordingly, the agency believes that the proposed rule is necessary and that it is consistent with the principles of Executive Order 12866; that it is not a significant regulatory action under that Executive Order; that it will not have a significant impact on a substantial number of small entities; and that it is not likely to result in an annual expenditure in excess of \$100 million.

**V. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Pub. L. 104-13) is not required.

**VI. Request for Comments**

Interested persons may, on or before March 22, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

**List of Subjects***21 CFR Part 2*

Administrative practice and procedure, Cosmetics, Drugs, Foods.

*21 CFR Part 3*

Administrative practice and procedure, Biologics, Drugs, Medical devices.

*21 CFR Part 5*

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

*21 CFR Part 10*

Administrative practice and procedure, News media.

*21 CFR Parts 12 and 16*

Administrative practice and procedure.

*21 CFR Part 20*

Confidential business information, Courts, Freedom of information, Government employees.

*21 CFR Part 25*

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

*21 CFR Part 50*

Human research subjects, Prisoners, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 54*

Biologics, Drugs, Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 56*

Human research subjects, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 58*

Laboratories, Reporting and recordkeeping requirements.

*21 CFR Part 60*

Administrative practice and procedure, Drugs, Food additives, Inventions and patents, Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 70*

Color additives, Cosmetics, Drugs, Labeling, Packaging and containers.

*21 CFR Part 71*

Administrative practice and procedure, Color additives, Confidential business information, Cosmetics, Drugs, Reporting and recordkeeping requirements.

*21 CFR Parts 200 and 300*

Drugs, Prescription drugs.

*21 CFR Part 201*

Drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 202*

Advertising, Prescription drugs.

*21 CFR Parts 206 and 299*

Drugs.

*21 CFR Parts 207 and 320*

Drugs, Reporting and recordkeeping requirements.

*21 CFR 210*

Drugs, Packaging and containers.

*21 CFR Part 211*

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

*21 CFR Part 310*

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 312*

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 314*

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

*21 CFR Part 316*

Administrative practice and procedure, Drugs, Reporting and recordkeeping requirements.

*21 CFR Part 333*

Labeling, Over-the-counter drugs.

*21 CFR Part 369*

Labeling, Medical devices, Over-the-counter drugs.

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 514*

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

*21 CFR Parts 520, 522, 524, and 529*

Animal drugs.

*21 CFR Part 800*

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

*21 CFR Part 801*

Labeling, Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 807*

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 809*

Labeling, Medical devices.

*21 CFR Part 812*

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

*21 CFR Part 860*

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 2, 3, 5, 10, 12, 16, 20, 25, 50, 54, 56, 58, 60, 70, 71, 200, 201, 202, 206, 207, 210, 211, 299, 300, 310, 312, 314, 316, 320, 333, 369, 510, 514, 520, 522, 524, 529, 800, 801, 807, 809, 812, and 860 be amended as follows:

**PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS**

1. The authority citation for 21 CFR part 2 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 335, 342, 346a, 348, 351, 352, 355, 360b, 361, 371, 372, 374; 15 U.S.C. 402, 409.

**PART 3—PRODUCT JURISDICTION**

2. The authority citation for 21 CFR part 3 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262.

**§ 3.2 [Amended]**

3. Section 3.2 *Definitions* is amended in paragraph (k) by removing “507,” and “antibiotic application.”.

**PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

4. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; 15 U.S.C. 1451–1461; 21 U.S.C. 41–50, 61–63, 141–149, 321–394, 467f, 679(b), 801–886, 1031–1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1; 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124–131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220–223.

**§ 5.31 [Amended]**

5. Section 5.31 *Petitions under part 10* is amended by removing and reserving paragraphs (f)(2)(v), (f)(2)(vi), and (f)(2)(vii).

**§ 5.70 [Amended]**

6. Section 5.70 *Issuance of notice implementing the provisions of the Drug Amendments of 1962* is amended by removing “sections 505 and 507” and adding in its place “section 505”.

**§ 5.75 [Removed]**

7. Section 5.75 *Designation of official master and working standards for antibiotic drugs* is removed.

**§ 5.76 [Removed]**

8. Section 5.76 *Certification of antibiotic drugs* is removed.

**§ 5.78 [Removed]**

9. Section 5.78 *Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs* is removed.

**PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES**

10. The authority citation for 21 CFR part 10 continues to read as follows:

**Authority:** 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

**§ 10.50 [Amended]**

11. Section 10.50 *Promulgation of regulations and orders after an*

*opportunity for a formal evidentiary public hearing* is amended by removing “314.300,” from paragraph (a)(2) and by removing and reserving paragraph (c)(11).

**§ 10.55 [Amended]**

12. Section 10.55 *Separation of functions; ex parte communications* is amended in paragraph (c) by removing “314.300,” from the first sentence.

**§ 10.80 [Amended]**

13. Section 10.80 *Dissemination of draft Federal Register notices and regulations* is amended in paragraph (g) by removing the phrase “or a proposed or final antibiotic regulation”.

**PART 12—FORMAL EVIDENTIARY PUBLIC HEARING**

14. The authority citation for 21 CFR part 12 is revised to read as follows:

**Authority:** 21 U.S.C. 141–149, 321–393, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b–263n, 264; 15 U.S.C. 1451–1461; 5 U.S.C. 551–558, 701–721; 28 U.S.C. 2112.

**§ 12.20 [Amended]**

15. Section 12.20 *Initiation of a hearing involving the issuance, amendment, or revocation of a regulation* is amended by removing “507(f),” from the introductory text of paragraph (a), by removing the phrase “or for an antibiotic petition in § 431.50” from paragraph (a)(2)(i), and by removing and reserving paragraph (c).

**§ 12.24 [Amended]**

16. Section 12.24 *Ruling on objections and requests for hearing* is amended by removing “314.300,” from paragraphs (b)(6) and (c).

**§ 12.87 [Amended]**

17. Section 12.87 *Purpose; oral and written testimony; burden of proof* is amended by removing “antibiotic,” from the first sentence of paragraph (d).

**PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION**

18. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

**§ 16.1 [Amended]**

19. Section 16.1 *Scope* is amended by removing §§ 431.52, 433.2(d), 433.12(b)(5), 433.13(b), 433.14(b), 433.15(b), 433.16(b), and 514.210 from the list of regulatory provisions in paragraph (b)(2).

**PART 20—PUBLIC INFORMATION**

20. The authority citation for 21 CFR part 20 is revised to read as follows:

**Authority:** 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

**§ 20.100 [Amended]**

21. Section 20.100 *Applicability; cross-reference to other regulations* is amended by removing and reserving paragraphs (c)(20) and (c)(21).

**§ 20.117 [Amended]**

22. Section 20.117 *New drug information* is amended by removing “antibiotic applications,” from paragraph (a)(3).

**PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS**

23. The authority citation for 21 CFR part 25 continues to read as follows:

**Authority:** 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

**§ 25.5 [Amended]**

24. Section 25.5 *Terminology* is amended by removing the phrase “, an abbreviated antibiotic application,” from paragraph (b)(1).

**§ 25.31 [Amended]**

25. Section 25.31 *Human drugs and biologics* is amended by removing paragraph (f) and redesignating paragraph (g) as paragraph (f), by removing paragraph (h), and by redesignating paragraph (i) through paragraph (l) as paragraph (g) through paragraph (j).

**PART 50—PROTECTION OF HUMAN SUBJECTS**

26. The authority citation for 21 CFR part 50 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

**§ 50.1 [Amended]**

27. Section 50.1 *Scope* is amended by removing “, 507(d),” from the first sentence of paragraph (a) and removing “507,” from the last sentence of paragraph (a).

**§ 50.3 [Amended]**

28. Section 50.3 *Definitions* is amended by removing and reserving

paragraph (b)(11) and removing “, 507(d),” from paragraph (c).

#### § 50.23 [Amended]

29. Section 50.23 *Exception from general requirements* is amended in paragraph (d)(1) by removing the phrase “(including an antibiotic or biological product)” and adding in its place the phrase “(including a biological product)”.

#### PART 54—FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS

30. The authority citation for 21 CFR part 54 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c–360j, 371, 372, 373, 374, 375, 376, 379; 42 U.S.C. 262.

#### § 54.4 [Amended]

31. Section 54.4 *Certification and disclosure requirements* is amended by removing “507,” from paragraph (a).

#### PART 56—INSTITUTIONAL REVIEW BOARDS

32. The authority citation for 21 CFR part 56 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 346, 346a, 348, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

#### § 56.101 [Amended]

33. Section 56.101 *Scope* is amended by removing “, 507(d),” from paragraph (a).

#### § 56.102 [Amended]

34. Section 56.102 *Definitions* is amended by removing paragraph (b)(10), by redesignating paragraph (b)(11) through paragraph (b)(21) as paragraph (b)(10) through paragraph (b)(20), and by removing “, 507(d),” from the first sentence of paragraph (c).

#### PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

35. The authority citation for 21 CFR part 58 is revised to read as follows:

**Authority:** 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

#### § 58.1 [Amended]

36. Section 58.1 *Scope* is amended by removing “507,” from paragraph (a).

#### § 58.3 [Amended]

37. Section 58.3 *Definitions* is amended by removing and reserving paragraph (e)(9).

#### PART 60—PATENT TERM RESTORATION

38. The authority citation for 21 CFR part 60 is revised to read as follows:

**Authority:** 21 U.S.C. 348, 355, 360e, 360j, 371, 379e; 35 U.S.C. 156; 42 U.S.C. 262.

#### § 60.3 [Amended]

39. Section 60.3 *Definitions* is amended by removing “507(d),” from paragraph (b)(5); by removing “, antibiotic drug,” from paragraph (b)(10); and by removing “or 507” from paragraphs (b)(11)(i) and (b)(12)(i).

40. Section 60.22 is amended by revising paragraphs (a)(1) and (2) to read as follows:

#### § 60.22 Regulatory review period determinations.

\* \* \* \* \*

(a) \* \* \*

(1) The testing phase begins on the date an exemption under section 505(i) of the Act becomes effective (or the date an exemption under former section 507(d) of the Act became effective) for the approved human drug product and ends on the date a marketing application under section 351 of the Public Health Service Act or section 505 of the act is initially submitted to FDA (or was initially submitted to FDA under former section 507 of the Act), and

(2) The approval phase begins on the date a marketing application under section 351 of the Public Health Service Act or section 505(b) of the Act is initially submitted to FDA (or was initially submitted under former section 507 of the Act) and ends on the date the application is approved.

\* \* \* \* \*

#### PART 70—COLOR ADDITIVES

41. The authority citation for 21 CFR part 70 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 360b, 361, 371, 379e.

#### § 70.10 [Amended]

42. Section 70.10 *Color additives in standardized foods, new drugs, and antibiotics* is amended by revising the heading to read “*Color additives in standardized foods and new drugs*”, by revising the heading of paragraph (b) to read “*New drugs*”, and by removing the phrases “or for certification of an antibiotic drug” from the first sentence of paragraph (b)(1), “or certification of an antibiotic drug” from the first sentence of paragraph (b)(2), and “or the request for certification of the antibiotic drug” from paragraph (b)(3).

#### PART 71—COLOR ADDITIVE PETITIONS

43. The authority citation for 21 CFR part 71 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

#### § 71.2 [Amended]

44. Section 71.2 *Notice of filing of petition* is amended by removing the phrase “or certifiable antibiotic” from the last sentence of paragraph (a).

#### PART 200—GENERAL

45. The authority citation for 21 CFR part 200 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360e, 371, 374, 375.

#### PART 201—LABELING

46. The authority citation for 21 CFR part 201 is revised to read as follows:

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

47. Section 201.59 is amended by revising paragraph (a)(1) to read as follows:

**§ 201.59 Effective date of §§ 201.56, 201.57, 201.100(d)(3), and 201.100(e).**

(a) \* \* \*

(1) If the drug is a prescription drug that is not a biologic and not subject to section 505 of the act (21 U.S.C. 355), and was not subject to former section 507 of the act (21 U.S.C. 357, repealed 1997), §§ 201.56, 201.57, and 201.100(d)(3) are effective on April 10, 1981.

\* \* \* \* \*

#### § 201.100 [Amended]

48. Section 201.100 *Prescription drugs for human use* is amended by removing “or 507” from paragraph (c)(2), and by removing “or 507” and “or 507, respectively” from paragraph (d)(1).

#### § 201.150 [Amended]

49. Section 201.150 *Drugs; processing, labeling, or repackaging* is amended by removing paragraphs (e) through (h).

#### PART 202—PRESCRIPTION DRUG ADVERTISING

50. The authority citation for 21 CFR part 202 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 352, 355, 360b, 371.

#### § 202.1 [Amended]

51. Section 202.1 *Prescription-drug advertisements* is amended by removing

paragraph (e)(4)(ii) and redesignating paragraph (e)(4)(iii) as paragraph (e)(4)(ii), by removing the words "paragraphs (e)(4)(i) and (ii)" from newly redesignated paragraph (e)(4)(ii) and by adding in their place the words "paragraph (e)(4)(i)", by removing "(e)(4)(iii)" and by adding in its place "(e)(4)(ii)" in paragraph (e)(6)(i), by removing ", 507, or 512" from paragraph (e)(6)(xvii), by removing the phrase "or antibiotic" from indefinitely stayed paragraph (e)(6)(ii)(a); and by removing the phrase "or a certified or released antibiotic," from indefinitely stayed paragraph (e)(6)(ii)(b).

#### **PART 206—IMPRINTING OF SOLID ORAL DOSAGE FORM DRUG PRODUCTS FOR HUMAN USE**

52. The authority citation for 21 CFR part 206 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 355, 371; 42 U.S.C. 262.

#### **PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION**

53. The authority citation for 21 CFR part 207 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 360, 360b, 371, 374; 42 U.S.C. 262.

#### **§ 207.20 [Amended]**

54. Section 207.20 *Who must register and submit a drug list* is amended by removing the words "an antibiotic application," from paragraph (c).

#### **§ 207.21 [Amended]**

55. Section 207.21 *Times for registration and drug listing* is amended by removing the words "antibiotic application," from the second sentence of paragraph (a).

#### **§ 207.25 [Amended]**

56. Section 207.25 *Information required in registration and drug listing* is amended by removing "507," and by removing the phrase "new animal drug application number, or antibiotic application number" from paragraph (b)(2) and by adding in its place the phrase "or new animal drug application number", by removing "or 507" from paragraph (b)(4), and by removing "507," from paragraph (b)(5) and paragraph (b)(6).

#### **§ 207.31 [Amended]**

57. Section 207.31 *Additional drug listing information* is amended by removing the phrase "or 507" from paragraph (a)(1) and by removing "507," from paragraphs (a)(2) and (a)(3), and paragraph (c).

#### **§ 207.35 [Amended]**

58. Section 207.35 *Notification of registrant; drug establishment registration number and drug listing number* is amended by removing the phrase ", or supplemental antibiotic application" from paragraph (b)(3)(v).

#### **§ 207.37 [Amended]**

59. Section 207.37 *Inspection of registrations and drug listings* is amended by removing "507," from paragraph (a)(2)(i).

#### **PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL**

60. The authority citation for 21 CFR part 210 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374.

#### **PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS**

61. The authority citation for 21 CFR part 211 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374.

#### **PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES**

62. The authority citation for 21 CFR part 299 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

#### **§ 299.4 [Amended]**

63. Section 299.4 *Established names for drugs* is amended by removing the phrase "or a new antibiotic drug" from the fifth sentence of paragraph (d).

#### **PART 300—GENERAL**

64. The authority citation for 21 CFR part 300 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 360b, 361, 371.

#### **§ 300.50 [Amended]**

65. Section 300.50 *Fixed-combination prescription drugs for humans* is amended by removing the words "or antibiotic monograph" from paragraph (b).

#### **PART 310—NEW DRUGS**

66. The authority citation for 21 CFR part 310 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

67. Section 310.502 is amended by revising the introductory text of paragraph (a) and removing and reserving paragraph (b) to read as follows:

#### **§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.**

(a) The drugs listed in this paragraph have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. An approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

\* \* \* \* \*

#### **PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

68. The authority citation for 21 CFR part 312 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

#### **§ 312.2 [Amended]**

69. Section 312.2 *Applicability* is amended by removing "or 507" from paragraph (a) and by removing "or antibiotic drug" from paragraph (d).

#### **§ 312.3 [Amended]**

70. Section 312.3 *Definitions and interpretations* is amended by removing ", antibiotic drug," from the paragraph defining "Investigational new drug" and by removing the phrase ", a request to provide for certification of an antibiotic submitted under section 507 of the Act," from the paragraph defining "Marketing application".

#### **SUBPART E—DRUGS INTENDED TO TREAT LIFE-THREATENING AND SEVERELY-DEBILITATING ILLNESSES**

71. The authority citation for 21 CFR part 312, subpart E is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 355, 371; 42 U.S.C. 262.

#### **§ 312.81 [Amended]**

72. Section 312.81 *Scope* is amended by removing ", antibiotic," from the introductory text.

73. Section 312.110 is amended by revising paragraph (b)(4) and by removing paragraph (b)(5) to read as follows:

#### **§ 312.110 Import and export requirements.**

\* \* \* \* \*

(b) \* \* \*

(4) This paragraph does not apply to the export of new drugs (including biological products, antibiotic drugs,

and insulin) approved or authorized for export under section 802 of the act (21 U.S.C. 382) or section 351(h)(1)(A) of the Public Health Service Act (42 U.S.C. 262(h)(1)(A)).

#### § 312.120 [Amended]

74. Section 312.120 *Foreign clinical studies not conducted under an IND* is amended by removing "or antibiotic drug" from the last sentence of paragraph (a).

#### § 312.130 [Amended]

75. Section 312.130 *Availability for public disclosure of data and information in an IND* is amended by removing "or antibiotic drug" from paragraph (b).

### PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

76. The authority citation for 21 CFR part 314 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371, 374, 379e.

77. The heading for part 314 is revised to read as set forth above.

78. Section 314.1 is amended by revising paragraph (a) to read as follows:

#### § 314.1 Scope of this part.

(a) This part sets forth procedures and requirements for the submission to, and the review by, the Food and Drug Administration of applications and abbreviated applications to market a new drug under section 505 of the Federal Food, Drug, and Cosmetic Act, as well as amendments, supplements, and postmarketing reports to them.

\* \* \* \* \*

#### § 314.50 [Amended]

79. Section 314.50 *Content and format of an application* is amended by removing "or 507" from the introductory text of paragraph (d).

#### § 314.81 [Amended]

80. Section 314.81 *Other postmarketing reports* is amended in paragraph (a) by removing the words "sections 505(k) and 507(g)" and by adding in their place the words "section 505(k)".

#### § 314.92 [Amended]

81. Section 314.92 *Drug products for which abbreviated applications may be submitted* is amended by removing and reserving paragraph (a)(2).

#### § 314.94 [Amended]

82. Section 314.94 *Content and format of an abbreviated application* is amended by removing and reserving paragraph (c) and paragraph (d)(3).

#### § 314.96 [Amended]

83. Section 314.96 *Amendments to an unapproved abbreviated application* is amended by removing paragraph (c).

#### § 314.98 [Amended]

84. Section 314.98 *Postmarketing reports* is amended in paragraph (a) by removing the phrase "approved abbreviated antibiotic application under § 314.94 or" and in paragraph (c) by removing the words "sections 505(k) and 507(g)" and by adding in their place the words "section 505(k)".

#### § 314.100 [Amended]

85. Section 314.100 *Timeframes for reviewing applications and abbreviated applications* is amended in paragraph (a) by removing the phrase "or of an application or abbreviated application for an antibiotic drug under section 507 of the act,".

#### § 314.101 [Amended]

86. Section 314.101 *Filing an application and an abbreviated antibiotic application and receiving an abbreviated new drug application* is amended by revising the heading to read "Filing an application and receiving an abbreviated new drug application", by removing the phrase "or abbreviated antibiotic application" each time it appears in this section, and by removing the phrase "or abbreviated antibiotic" in the first sentence of paragraph (a)(2).

#### § 314.105 [Amended]

87. Section 314.105 *Approval of an application and an abbreviated application* is amended by removing the phrases "or an abbreviated antibiotic application" and "or abbreviated antibiotic application" from the first sentence of paragraph (a), by removing the fourth and sixth sentences of paragraph (a), and by removing the phrase "or abbreviated antibiotic application" from the first sentence of paragraph (b) both times it appears.

#### § 314.110 [Amended]

88. Section 314.110 *Approvable letter to the applicant* is amended by removing the phrases "or abbreviated antibiotic application", "or an abbreviated antibiotic application", and "or the abbreviated antibiotic application" each time they appear in this section; by removing and reserving paragraph (a)(4); by removing "or (a)(4)" from the first sentence of paragraph (a)(5); and by removing the words "under § 314.99" from paragraph (a)(2) and paragraph (a)(5).

#### § 314.120 [Amended]

89. Section 314.120 *Not approvable letter to the applicant* is amended by

removing the phrase "or abbreviated antibiotic application" from the first sentence of the introductory text of paragraph (a) and from the third sentence of paragraph (a)(3), by adding the word "or" to the end of paragraph (a)(3), by removing and reserving paragraph (a)(4), and by removing the phrase "(a)(3), or (a)(4)" and adding in its place "or (a)(3)" in the first sentence of paragraph (a)(5).

#### § 314.125 [Amended]

90. Section 314.125 *Refusal to approve an application or abbreviated antibiotic application* is amended by revising the heading to read "Refusal to approve an application"; by removing the phrase "or abbreviated antibiotic application" each time it appears in this section; by removing the phrase "or for an antibiotic publish a proposed regulation based on an acceptable petition under § 314.300," from the introductory text of paragraph (a); by removing the phrase "or files a petition for an antibiotic proposing the issuance, amendment, or repeal of a regulation" from paragraph (a)(2); and by removing "or 507" from paragraph (b)(2).

#### § 314.126 [Amended]

91. Section 314.126 *Adequate and well-controlled studies* is amended in paragraph (a) by removing the word "sections" and adding in its place the word "section" and removing the words "and 507" from the third sentence and by removing the words "and antibiotics" from the fourth sentence.

#### § 314.150 [Amended]

92. Section 314.150 *Withdrawal of approval of an application or abbreviated application* is amended by removing the phrase "or, for an antibiotic, rescind a certification or release, or amend or repeal a regulation providing for certification under section 507 of the act and under the procedure in § 314.300," from the introductory text of paragraphs (a) and (b).

93. Section 314.170 is amended by revising the first sentence and by removing the phrase "and approved antibiotic drugs" from the second sentence to read as follows:

#### § 314.170 Adulteration and misbranding of an approved drug.

All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act. \* \* \*

#### Subpart F [Removed and Reserved]

94. Subpart F, consisting of § 314.300, is removed and reserved.



95. Section 314.410 is amended by revising the heading, by removing the phrase "or an antibiotic" from paragraph (a)(1), by removing the phrase "or, in the case of an antibiotic not exempt from certification under part 433, it is also certified or released" from paragraph (a)(1)(i), by removing the phrases "or an antibiotic" and "and, in the case of an antibiotic, it is certified or released," from paragraph (b)(1), and by revising paragraph (b)(3) to read as follows:

**§ 314.410 Imports and exports of new drugs.**

\* \* \* \* \*

(b) \* \* \*

(3) Insulin or an antibiotic drug may be exported without regard to the requirements in section 802 of the act if the insulin or antibiotic drug meets the requirements of section 801(e)(1) of the act.

**§ 314.430 [Amended]**

96. Section 314.430 *Availability for public disclosure of data and information in an application or abbreviated application* is amended by removing paragraph (e)(8) and in paragraph (f)(6) by removing "sections 505(j) and 507" and adding in its place "section 505".

**§ 314.500 [Amended]**

97. Section 314.500 *Scope* is amended by removing the phrase "and antibiotic".

**§ 314.530 [Amended]**

98. Section 314.530 *Withdrawal procedures* is amended by removing the phrase "and antibiotics" from paragraph (a).

**PART 316—ORPHAN DRUGS**

99. The authority citation for 21 CFR part 316 continues to read as follows:

**Authority:** 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

**§ 316.3 [Amended]**

100. Section 316.3 *Definitions* is amended by removing the phrase "a request for certification of an antibiotic under section 507 of the act," from paragraph (b)(9).

**PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS**

101. The authority citation for 21 CFR part 320 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 371.

**§ 320.38 [Amended]**

102. Section 320.38 *Retention of bioavailability samples* is amended by removing "or 507" from paragraph (a).

**§ 320.63 [Amended]**

103. Section 320.63 *Retention of bioequivalence samples* is amended by removing "or 507" from the first sentence.

**PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

104. The authority citation for 21 CFR part 333 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

**§ 333.103 [Amended]**

105. Section 333.103 *Definitions* is amended by removing paragraph (a) and by removing the designation for paragraph (b).

**§ 333.110 [Amended]**

106. Section 333.110 *First aid antibiotic active ingredients* is amended in paragraph (a) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510a(b)"; in paragraph (b) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513f(b)"; in paragraph (c) by removing the phrase "Provided, That it meets the tests and methods of assay in § 446.510(b)"; in paragraph (d) by removing the phrase "Provided, That it meets the tests and methods of assay in § 444.542a(b)"; in paragraph (e) by removing the phrase "Provided, That it meets the tests and methods of assay in § 444.542b(b)"; and in paragraph (f) by removing the phrase "Provided, That it meets the tests and methods of assay in § 446.581d(b)".

**§ 333.120 [Amended]**

107. Section 333.120 *Permitted combinations of active ingredients* is amended in paragraph (a)(1) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510d(b)"; in paragraph (a)(2) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510e(b)"; in paragraph (a)(3) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510f(b)"; in paragraph (a)(4) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513b(b)"; in paragraph (a)(5) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513c(b)"; in paragraph (a)(6) by removing the phrase "Provided, That it meets the tests and methods assay in § 448.513a(b)"; in paragraph (a)(7) by

removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513e(b) of this chapter"; in paragraph (a)(8) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513d(b)"; in paragraph (a)(9) by removing the phrase "Provided, That it meets the tests and methods of assay in § 444.542e(b)"; in paragraph (a)(10) by removing the phrase "Provided, That it meets the tests, methods of assay, and potency in § 444.5421(b)"; in paragraph (a)(11) by removing the phrase "Provided, That it meets the tests and methods assay in § 446.567b(b)"; in paragraph (a)(12) by removing the phrase "Provided, That it meets the tests and methods assay in § 446.567c(b)"; in paragraph (b)(1) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510a(b)"; in paragraph (b)(2) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510e(b)"; in paragraph (b)(3) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.510f(b) of this chapter"; in paragraph (b)(4) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513c(b) of this chapter"; in paragraph (b)(5) by removing the phrase "Provided, That it meets the tests and methods of assay in § 448.513a(b) of this chapter"; and in paragraph (b)(6) by removing the phrase "Provided, That it meets the tests and methods of assay in § 444.5421(b) of this chapter".

**PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE**

108. The authority citation for 21 CFR part 369 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

**PART 510—NEW ANIMAL DRUGS**

109. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.45 [Removed]**

110. Section 510.45 *Packaging requirements for drugs for animal use* is removed.

**§ 510.110 [Amended]**

111. Section 510.110 *Antibiotics used in food-producing animals* is amended by removing the phrase "to amend or revoke antibiotic regulations under the provisions of section 507 of the act, or" in paragraph (e), by removing the phrase



“(except certifiable antibiotics)” in the first sentence of paragraph (f), and by removing the last sentence of paragraph (f).

#### **PART 514—NEW ANIMAL DRUG APPLICATIONS**

112. The authority citation for 21 CFR part 514 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

#### **§ 514.10 [Removed]**

113. Section 514.10 *Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug* is removed.

#### **PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

114. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### **§ 520.1204 [Amended]**

115. Section 520.1204 *Kanamycin sulfate, aminopentamide hydrogen sulfate, pectin, bismuth subcarbonate, activated attapulgit suspension* is amended in paragraph (a) by removing the phrase “(the kanamycin used conforms to the standards of identity, strength, quality, and purity prescribed by § 444.30 of this chapter)”.

116. Section 520.1263a is amended by revising paragraph (a) to read as follows:

#### **§ 520.1263a Lincomycin hydrochloride monohydrate tablets and sirup.**

(a) *Specifications.* The sirup contains lincomycin hydrochloride equivalent to either 25 milligrams or 50 milligrams of lincomycin.

\* \* \* \* \*

#### **§ 520.1263b [Amended]**

117. Section 520.1263b *Lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate soluble powder* is amended by removing the first complete sentence in paragraph (a).

#### **PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

118. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

119. Section 522.1204 is amended by revising paragraph (a) to read as follows:

#### **§ 522.1204 Kanamycin sulfate injection.**

(a) *Specifications.* Each milliliter of kanamycin sulfate injection veterinary

contains either 50 or 200 milligrams of kanamycin.

\* \* \* \* \*

#### **§ 522.1484 [Amended]**

120. Section 522.1484 *Neomycin sulfate sterile solution* is amended by removing the second sentence of paragraph (a) but retaining footnote 1 at the end of paragraph (a).

#### **PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

121. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### **§ 524.1200a [Amended]**

122. Section 524.1200a *Kanamycin ophthalmic ointment* is amended by removing paragraph (a)(1) and by removing the designation for paragraph (a)(2).

123. Section 524.1200b is amended by revising paragraph (a) to read as follows:

#### **§ 524.1200b Kanamycin ophthalmic aqueous solution.**

(a) *Specifications.* The drug, which is in an aqueous solution including suitable and harmless preservatives and buffer substances, contains 10 milligrams of kanamycin activity (as the sulfate) per milliliter of solution.

\* \* \* \* \*

#### **§ 524.1204 [Amended]**

124. Section 524.1204 *Kanamycin sulfate, calcium amphotycin, and hydrocortisone acetate* is amended by removing paragraph (a)(1), by redesignating paragraphs (a)(2)(i) through (a)(2)(iii) as paragraphs (a)(1)(i) through (a)(1)(iii), and by redesignating paragraph (a)(3) as paragraph (a)(2).

#### **PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

125. The authority citation for 21 CFR part 529 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

#### **§ 529.360 [Amended]**

126. Section 529.360 *Cephalothin discs* is amended by removing the phrase “, comply with the requirements of § 460.1 of this chapter” from paragraph (a) and adding in its place “have a uniform potency of 30 micrograms cephalothin per disc”.

#### **PART 800—GENERAL**

127. The authority citation for 21 CFR part 800 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

#### **PART 801—LABELING**

128. The authority citation for 21 CFR part 801 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

#### **PART 807—ESTABLISHMENT AND REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND DISTRIBUTORS OF DEVICES**

129. The authority citation for 21 CFR part 807 continues to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

#### **§ 807.25 [Amended]**

130. Section 807.25 *Information required or requested for establishment registration and device listing* is amended by removing “, 507,” in paragraph (f)(3).

#### **PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE**

131. The authority citation for 21 CFR part 809 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

#### **§ 809.5 [Removed]**

132. Section 809.5 *Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act* is removed.

#### **§ 809.6 [Removed]**

133. Section 809.6 *Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements* is removed.

#### **PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS**

134. The authority citation for 21 CFR part 812 is revised to read as follows:

**Authority:** 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

#### **PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES**

135. The authority citation for 21 CFR part 860 continues to read as follows:

**Authority:** 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

#### **§ 860.84 [Amended]**

136. Section 860.84 *Classification procedures for “old devices”* is amended by removing the fourth sentence in paragraph (a).

Dated: December 12, 1998.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 99-141 Filed 1-4-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 315 and 601

[Docket No. 98D-0785]

#### Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Availability of guidance; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until February 12, 1999, the comment period for the draft guidance for industry entitled "Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics" that appeared in the **Federal Register** of October 14, 1998 (63 FR 55067). FDA is taking this action in response to a request for an extension.

**DATES:** Written comments on the draft guidance may be submitted by February 12, 1999. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Robert K. Leedham, Center for Drug Evaluation and Research (HFD-160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-

7510, or

George Q. Mills, Center for Biologics Evaluation and Research (HFM-573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5097.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance document for industry entitled "Developing Medical Imaging Drugs and Biologics." The draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency would interpret and apply provisions in proposed regulations, published in the **Federal Register** of May 22, 1998 (63 FR 28301), for in vivo radiopharmaceuticals used for diagnosis and monitoring. The draft guidance applies to medical imaging drugs that are used for diagnosis and monitoring and that are administered in vivo. The draft guidance is not intended to apply to possible therapeutic uses of these drugs or to in vitro diagnostic products. Interested persons were given until December 14, 1998, to submit written comments on the draft guidance.

FDA received a letter, dated December 4, 1998, from Alan M. Kirschenbaum, legal counsel for the Council on Radionuclides and Radiopharmaceuticals, requesting that the agency extend the comment period on the draft guidance by 60 days.

The draft guidance introduces several new and highly technical issues. Therefore, the agency has decided to reopen the comment period on the draft guidance until February 12, 1999, to allow the public more time to review and comment on its contents.

Interested persons may, on or before February 12, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 28, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 99-72 Filed 1-4-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 801

[REG 119192-98]

RIN 1545-AW80

#### Establishment of a Balanced Measurement System

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains proposed regulations relating to the adoption by the IRS of a balanced system to measure organizational performance within the IRS. These proposed regulations further implement a requirement that all employees be evaluated on whether they provided fair and equitable treatment to taxpayers and bar use of records of tax enforcement results to evaluate or to impose or suggest goals for any employee of the IRS. These regulations implement sections 1201 and 1204 of the Internal Revenue Restructuring and Reform Act of 1998. These regulations affect internal operations of the IRS and the systems that agency employs to evaluate the performance of organizations within IRS and individuals employed by IRS. This document also provides notice of public hearing on these proposed regulations.

**DATES:** Written comments and electronic comments must be received by March 8, 1999. Outlines of oral comments to be presented at the public hearing scheduled for Thursday, May 13, 1999 at 10 a.m. must be received by Thursday, April 22, 1999.

**ADDRESSES:** Send submissions to: CC:DOM:CORP:R (REG-119192-98), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG-119192-98), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the "Tax Regs" option on