

Action is taken herein to correct this reference in AD 98-11-01 R2 and to add this AD correction to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The effective date remains September 22, 1998.

Issued in Kansas City, Missouri, on December 29, 1998.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to remove references to the repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs. FDA is also removing references to the repealed antibiotic monograph regulations and to those regulations dealing with antibiotic applications.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). Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: This rule is effective May 20, 1999. Submit written comments on or before March 22, 1999. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before April 20, 1999, confirming the effective date of the direct final rule. The agency

intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before April 20, 1999.

ADDRESSES: Submit written comments 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

On November 21, 1997, the President signed FDAMA (Pub. L. 105-115). Section 125(b) of FDAMA repealed section 507 of the act (21 U.S.C. 357). Section 507 of the act was the statutory provision under which the agency certified antibiotic drugs. Section 125(b) of FDAMA also made conforming amendments to other sections of the act. With the repeal of section 507 of the act, antibiotic drugs previously regulated under section 507 will be subject to the provisions of section 505 of the act (21 U.S.C. 355).

FDA has determined that it will be most efficient to make changes in its regulations to reflect the repeal of section 507 of the act in phases. In the first phase, FDA published in the **Federal Register** of May 12, 1998 (63 FR 26066), a direct final rule removing parts 430 through 460 (21 CFR parts 430 through 460), which had provided the procedures and standards used to certify antibiotic drugs. This direct final rule is the second phase of rulemaking in which the agency is making various, noncontroversial conforming amendments to the balance of Title 21 of the Code of Federal Regulations. The rule removes citations to section 507 of the act. It removes references to the certification of antibiotics, to the antibiotic certification regulations, and to specific antibiotic monographs. It also removes references to antibiotic drug applications, abbreviated antibiotic drug

applications, and supplemental drug antibiotic applications.

The agency recognizes that as it implements the transition from regulating the premarket review and approval of antibiotic drugs under section 507 of the act to section 505 of the act, other issues may arise that could require additional rulemaking. These issues will be addressed in the third phase of implementation.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. The repeal of section 507 of the act eliminates the statutory provision on which the agency relied to certify antibiotic drugs. FDA will, therefore, remove all provisions of Title 21 of the Code of Federal Regulations that were issued primarily to carry out the agency's certification of antibiotic drugs under former section 507 of the act. All direct references to section 507 of the act will be removed, as well as all references to regulations that were issued to carry out programs under section 507 and all references to forms and applications that were unique to the regulation of antibiotics under section 507. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comments on this rule.

If FDA does not receive significant adverse comment on or before March 22, 1999, the agency will publish a document in the **Federal Register** before April 20, 1999, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. 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. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before April 20, 1999.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, which is identical to the direct final rule, that provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn

because of significant adverse comment. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule. Likewise, significant adverse comments submitted to the direct final rule will be considered as comments to the companion proposed rule and the agency will consider such comments in developing a final rule. FDA will not provide additional opportunity for comment on the companion proposed rule.

If a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision may be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the **Federal Register** of November 21, 1997 (62 FR 62466).

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a class of actions that do 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 impacts of the direct final 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. As discussed in this section of this document, the agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the direct final 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, for the reasons discussed below, that the direct final 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 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 rule is intended to make conforming changes to FDA's regulations necessitated by repeal of the section 507 of the act that had provided for the certification of antibiotic drugs. Accordingly, the agency believes that the 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

This direct final rule does not require information collections and, thus, is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Pub. L. 104-13).

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 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.

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, 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 are 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.

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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, 306bb, 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 of 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 of assay in § 446.567b(b)””; in paragraph (a)(12) by removing the phrase “: *Provided*, That it meets the tests and methods of 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 attapulgitte 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 amphotericin, 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 16, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 99–140 Filed 1–4–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 78N–0281]

Direct Food Substances Affirmed as Generally Recognized as Safe; Magnesium Hydroxide; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on food for human consumption to correct an error in the Chemical Abstracts Service (CAS) registry number for magnesium hydroxide. This document corrects that error.

DATES: This regulation is effective January 5, 1999.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of April 5, 1985 (50 FR 13557), the agency amended its regulations by adding § 184.1428 (21 CFR 184.1428) to affirm that magnesium hydroxide is generally recognized as safe (GRAS) as a direct human food ingredient. The CAS registry number for magnesium hydroxide was incorrectly published as “(Mg(OH)₂, CAS Reg. No. 1409–42–8)” instead of “(Mg(OH)₂, CAS Reg. No. 1309–42–8)”. Accordingly, the agency is amending § 184.1428 to correct the error.

Publication of this document constitutes final action on this change. Notice and public procedure are unnecessary because FDA is merely correcting a nonsubstantive error in its regulations.

List of Subjects in 21 CFR Part 184

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows: