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with the applicable CFMI SB listed in paragraph (b) of this AD.

Alternate Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Ferry Flights

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the inspection requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on January 14, 2000.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00–1641 Filed 1–21–00, 8:45 am]

BILLING CODE 4910–13–U

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038–AB50

Proposed Revision of the Commission's Procedures for the Review of Contract Market Rules

AGENCY: Commodity Futures Trading Commission.

ACTION: Extension of comment period.

SUMMARY: On November 26, 1999, the Commodity Futures Trading Commission ("Commission") published in the **Federal Register** a request for public comment on a proposal to revise its procedures for the review of contract market rules and rule amendments (64 FR 66428). The original comment period expires January 25, 2000. By letter dated January 3, 2000, seven agricultural organizations requested a thirty day extension of the comment period to permit the membership of each organization to fully consider the implications of the proposed procedures.[1]

The Commission has determined to extend the comment period for thirty days in order to insure that an adequate opportunity is provided for submission of meaningful comments.

EFFECTIVE DATE: Written comments must be received on or before February 24, 2000.

ADDRESSES: Comments on the proposal should be sent to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW, Washington, DC 20581. Comments may be sent by facsimile transmission to (202) 418–5521, or by e-mail to secretary @cftc.gov. Reference should be made to "Procedure for the Review of Contract Market Rules".

FOR FURTHER INFORMATION CONTACT: David P. Van Wagner, Associate Director, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW, Washington, DC 20581. Telephone Number: (202) 418–5490. Facsimile Number: (202) 418–5536. Electronic Mail: tm@cftc.gov.

Issued in Washington, D.C. on January 18, 2000 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 00–1568 Filed 1–21–00, 8:45 am]

BILLING CODE 6351–01–M

[1] The request was made in a January 3, 2000 letter jointly signed by the American Farm Bureau Federation, the American Soybean Association, the National Association of Wheat Growers, the National Cattlemen's Beef Association, the National Corn Grower's Association, the National Farmers Union, and the National Pork Producers Council.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 99N–3088]

RIN 0910–AB33

Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations to exempt marketing applications for certain antibiotic drug products from regulatory provisions governing marketing exclusivity and patents. The proposal would apply to marketing applications for drug products containing an antibiotic drug that was the subject of a marketing application received by FDA before November 21, 1997, the effective date of the Food and Drug Administration Modernization Act of 1997 (Modernization Act). This action is intended to bring the agency's regulations into conformance with certain transitional provisions of the Modernization Act. FDA is including in the proposed regulation a list of the active moieties of antibiotic drugs that were the subjects of marketing applications received by FDA before November 21, 1997.

DATES: Written comments by April 24, 2000.

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: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. The Modernization Act

On November 21, 1997, the President signed the Modernization Act (Public Law 105–115). Section 125(b) of the Modernization Act repealed section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357 (1996)). Section 507 was the section of the act under which the agency certified antibiotic drugs. Section 125(b) of the Modernization Act also made conforming amendments to the act.

In the **Federal Register** of May 12, 1998 (63 FR 26066), and January 5, 1999 (64 FR 396), the agency issued conforming amendments to its regulations to remove provisions governing certification of antibiotic drugs (21 CFR parts 430 to 460) and to make other changes needed to reflect the repeal of section 507 of the act.

Section 125(d)(1) of the Modernization Act provides that marketing applications for antibiotic drugs that were approved under former section 507 of the act will be considered to have been submitted and approved under the new drug application (NDA) submission and approval provisions found at section 505(b) and (c) of the act (21 U.S.C. 355(b) and (c)). If the marketing application was an approved abbreviated antibiotic drug application, it will be considered to have been submitted and approved under the abbreviated new drug application (ANDA) provisions found in section 505(j) of the act.

The Modernization Act also exempts certain antibiotic-related drug marketing applications from the marketing exclusivity and patent provisions found

in section 505 of the act.[1] Under former section 507 of the act, antibiotic drug applications were not subject to the patent listing and exclusivity provisions in section 505 of the act. Section 125 of the Modernization Act preserves this distinction with an expansive line Section 125 exempts those applications that contain an antibiotic drug that was the subject of a marketing application received by FDA under former section 507 of the act before November 21, 1997 (prerepeal antibiotic drugs). Drugs that were approved and marketed under former section 507 of the act, as well as those that were the subject of applications that may have been withdrawn, not filed, or refused approval under section 507 of the act are excluded from the patent listing and exclusivity provisions.

Specifically, section 125(d)(2) of the Modernization Act provides that marketing applications for drug products that contain prerepeal antibiotic drugs are not subject to the following provisions of section 505 of the act:

- The third and fourth sentences of section 505(b)(1) (requiring submission of patent information in NDA's).
- Section 505(b)(2)(A) (requiring that 505(b)(2) applications contain patent certifications).
- Section 505(b)(2)(B) (requiring that applications submitted under section 505(b)(2) of the act (505(b)(2) applications) contain a statement about relevant method of use patents).
- Section 505(b)(3) (requiring applicants submitting 505(b)(2) applications (505(b)(2) applicants) to provide notice to the patent owner and NDA holder of the certification of invalidity or noninfringement of a patent).
- Section 505(c)(2) (requiring submission of patent information if that information becomes available after an NDA is submitted).
- Section 505(c)(3) (providing for delayed effective dates of approval of 505(b)(2) applications under patent provisions of the act).
- Section 505(d)(6) (allowing FDA to refuse to approve an application that does not contain required patent information).
- Section 505(e)(4) (requiring FDA to withdraw approval of an application if the applicant refuses to submit required patent information).
- Section 505(j)(2)(A)(vii) and (j)(2)(A)(viii) (requiring ANDA's to contain patent certifications or other patent information).
- Section 505(j)(2)(B) (requiring ANDA applicants to provide notice to the patent owner and NDA holder of the certification of invalidity or noninfringement of a patent).
- Section 505(j)(5)(B) (providing for delayed effective dates of approval of ANDA's under patent provisions of the act).[2]
- Section 505(j)(5)(D) (describing submission of and effective dates of approval of ANDA's under marketing exclusivity provisions of the act).

Section 125(d)(3) of the Modernization Act authorizes FDA to make available to the public the established name of each antibiotic drug that was the subject of a marketing application received by FDA under former section 507 of the act before November 21, 1997.

II. Description of the Rule

A. List of Regulatory Provisions That Are Not Applicable

This proposed rule would exempt from the regulatory requirements that correspond to the statutory requirements described above, applications or abbreviated applications in which the drug product that is the subject of the application contains a pre-repeal antibiotic drug. Specifically, under the proposed rule, the following provisions found in part 314 (21 CFR part 314) would not apply to marketing applications for drug products that contain pre-repeal antibiotic drugs:

- Sections 314.50(h) and 314.53 (relating to submission of patent information in NDA's).
- Section 314.50(i) (relating to patent certifications and statements about relevant method of use patents in 505(b)(2) applications).
- Section 314.52 (relating to notices to the patent owner and NDA holder of certification of invalidity or noninfringement of a patent by 505(b)(2) applicants).
- Section 314.94(a)(12) (relating to patent certifications and statements about relevant method of use patents in ANDA's).
- Section 314.95 (relating to notices to the patent owner and NDA holder of certification of invalidity or noninfringement of a patent by ANDA applicants).
- Section 314.107(b) through (f) (relating to delayed effective dates of approval of ANDA's and 505(b)(2) applications under patent provisions of the act).
- Section 314.108(b) (relating to submission of and effective dates of approval of ANDA's and 505(b)(2) applications under marketing exclusivity provisions of the act).
- Section 314.125(b)(18) (relating to refusal to approve an NDA that does not contain required patent information).
- Section 314.150(a)(2)(v) (relating to withdrawal of approval of an NDA if the applicant refuses to submit required patent information).

The brief parenthetical descriptions of the various provisions of part 314 in this section and in the codified portion of this proposed rule (as well as the similar descriptions of provisions of section 505 of the act given in section I of this document) are provided merely as aids to the reader in understanding the scope of the proposed rule. They are not intended to have any regulatory significance and should not be understood to be statements of agency policy regarding the provisions they describe.

B. List of Pre-Repeal of Antibiotic Drugs

In applying section 125(d)(2) of the Modernization Act, the agency must determine whether a drug that is the subject of an NDA or ANDA contains a pre-repeal antibiotic drug. As described in section I, the Modernization Act specifies patent listing and exclusivity provisions that will not apply when the drug that is the subject of any application contains an antibiotic drug, and the antibiotic drug was the subject of any application received under section 507 of the act prior to November 21, 1997. Section 125(d)(3) of the Modernization Act also authorizes FDA to publish the established name of each antibiotic drug that was the subject of any application for marketing received by FDA under former section 507 of the act.

The term "antibiotic drug," as used in section 125(d) of the Modernization Act, is defined as:

> * * * any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof

21 U.S.C. 321(jj)

Thus, the term "antibiotic drug" includes not only the "chemical substance which is produced by a

[1] The Modernization Act does not affect whatever rights patent holders may have regarding patent term extensions under 35 U S C. 156 for patents claiming antibiotic drug products

[2] The Modernization Act added a new section 505(j)(3) to the act This resulted in the renumbering of sections 505(j)(3) through (j)(8) as sections 505(j)(4) through (j)(9), respectively

micro-organism," and which "has the capacity to inhibit or destroy micro-organisms," but also "any derivative" of any such substance, such as a salt or ester of the substance.

For this reason, and the reasons discussed below, the determination under section 125(d) of the Modernization Act of whether a drug contains a pre-repeal antibiotic depends on whether the drug that is the subject of a marketing application contains an active moiety that can be found in a pre-repeal antibiotic drug.

An active moiety is the molecule or ion responsible for physiological or pharmacological action, excluding appended portions that would cause the drug to be an ester, salt, or other noncovalent derivative of the molecule (see § 314.108(a)). FDA has consistently looked at active moieties to determine if the exclusivity protection granted to a drug product would allow a subsequent ANDA or application described in section 505(b)(2) of the act to be submitted or approved.

The agency's primary regulation governing marketing exclusivity is found at § 314.108. This regulation, which was proposed in the **Federal Register** of July 10, 1989 (54 FR 28872), and made final in the **Federal Register** of October 3, 1994 (59 FR 50338), incorporated an interpretation of the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the Hatch-Waxman Amendments) that had been adopted by the agency shortly after the enactment of the Hatch-Waxman Amendments on September 24, 1984. The Hatch-Waxman Amendments established the exclusivity and patent provisions that are addressed by the exemptions described in section 125(d)(2) of the Modernization Act, and are the subject of this rulemaking. In interpreting the exclusivity provisions in the Hatch-Waxman Amendments, the agency concluded that Congress did not intend to confer significant periods of exclusivity on minor variations of previously approved chemical compounds. (See, e.g., Congressional Record H9124 (September 6, 1984) (statement of Representative Waxman); H. Rept. 857, Part I, 98th Cong., 2d sess. 38 (1984).) Therefore, the agency determined that it is appropriate to assess whether the drug seeking exclusivity is a new chemical entity, that is, a drug that does not contain any previously approved active moiety.

This approach is also consistent with FDA's drug classification system, which assesses and classifies NDA's based upon the characteristics of the active ingredient or ingredients of the product. (See 54 FR 28872 at 28897.)

The language of section 125(d)(2) of the Modernization Act likewise supports the conclusion that Congress did not intend to confer exclusivity on, or require patent listing for, products that represent minor or incremental variations on pre-repeal antibiotic drugs. As discussed above, Congress in section 125(d)(2) of the Modernization Act chose to exclude all drugs containing pre-repeal "antibiotic drugs," a term that by definition includes the active drug substance and "any derivative thereof" (see section 201(jj) of the act (21 U.S.C. 321(jj)).

Accordingly, the agency is proposing to implement section 125(d)(2) of the Modernization Act by relying on a comparison of active moieties to determine whether the drug that is the subject of an NDA contains a pre-repeal antibiotic drug. NDA's for products that contain, for example, a salt of a pre-repeal antibiotic drug, or that propose such things as a new manufacturing process, new dosage form, or new use of a pre-repeal antibiotic drug, will be subject to the exceptions listed in section 125(d)(2) of the Modernization Act and proposed § 314.109(a).

To help interested persons determine which drug products would be exempt from the marketing exclusivity and patent provisions described above, FDA will maintain in the Code of Federal Regulations a list of the names of each pre-repeal active moiety. A proposed version of that list is included as § 314.109(b).

The list will provide all of the information required for an interested person to determine whether a marketing application is for a drug that contains a pre-repeal antibiotic drug. The list is intended to be comprehensive, but the inadvertent omission of an active moiety found in a pre-repeal antibiotic drug will not affect the regulatory status of a marketing application for a drug that contains that active moiety; the application will still be exempt from the statutory and regulatory requirements regarding marketing exclusivity and patents described above. A person who believes that a drug has been improperly included or omitted from the list should submit to the Dockets Management Branch (address above) written comments suggesting amendments to the list, along with any information that supports the suggested amendments. Comments should be identified with the docket number found in brackets in the heading of this document.

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 impacts 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 (Public Law 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. Because, the proposed rule is a significant regulatory action as defined by the Executive Order and it was subject to review under the Executive Order.

The Regulatory Flexibility Act requires that if a rule has a significant economic 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 proposed rule will not have a significant economic 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 one year. Exempting applications for certain antibiotic drugs from regulatory provisions dealing with marketing exclusivity and patent information 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 by any governmental entity or the private sector, no budgetary impact statement is required.

This proposed rule is intended to bring FDA's regulations governing the new drug approval process into conformance with the transitional provisions found in section 125(d)(2) of the Modernization Act This proposed rule is not intended to create any rights or responsibilities that are not found in the statute. For these reasons, the agency believes that this 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 economic 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 is not required.

VI. Request for Comments

Interested persons may, on or before April 24, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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 in 21 CFR Part 314

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

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 part 314 be amended as follows:

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

1. 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; sec 125(d), Pub. L. 105–115, 111 Stat 2296.

2. Add § 314.109 to subpart D to read as follows:

§ 314.109 Marketing exclusivity and patent provisions not applicable to certain antibiotic-related drug marketing applications.

(a) The following regulatory provisions do not apply to any application or abbreviated application in which the drug that is the subject of the application or abbreviated application contains an antibiotic drug that has the same active moiety (as defined in § 314.108(a)) as an antibiotic drug that was the subject of a marketing application received by FDA under former section 507 of the act (21 U.S.C. 357 (1996)) before November 21, 1997:

(1) Sections 314.50(h) and 314.53 (relating to submission of patent information in applications).

(2) Section 314.50(i) (relating to patent certifications and statements about relevant method of use patents in 505(b)(2) applications).

(3) Section 314.52 (relating to notices of certification of invalidity or noninfringement of a patent by 505(b)(2) applicants).

(4) Section 314.94(a)(12) (relating to patent certifications and statements about relevant method of use patents in 505(j) applications).

(5) Section 314.95 (relating to notices of certification of invalidity or noninfringement of a patent by 505(j) applicants).

(6) Section 314.107(b) through (f) (relating to delayed effective dates of approval of 505(j) applications and 505(b)(2) applications under patent provisions of the act).

(7) Section 314.108(b) (relating to submission of and effective dates of approval of 505(j) applications and 505(b)(2) applications under marketing exclusivity provisions of the act).

(8) Section 314.125(b)(18) (relating to refusal to approve an application that does not contain required patent information).

(9) Section 314.150(a)(2)(v) (relating to withdrawal of approval of an application if the applicant refuses to submit required patent information).

(b) The following are the active moieties of antibiotic drugs that were the subject of marketing applications received by FDA under former section 507 of the act before November 21, 1997. The list is intended to be comprehensive, but the inadvertent omission of an active moiety will not affect the regulatory status of a marketing application for a drug product that contains that active moiety.

Almecillin
Amdinocillin
Amikacin
Amoxicillin
Amphomycin
Amphotericin B
Ampicillin
Azacitidine
Azaserine
Azithromycin
Azlocillin
Aztreonam
Bacampicillin
Bacitracin
Benzyl penicilloyl-polylysine
Bleomycin
Candicidin
Capreomycin
Carbenicillin
Cefaclor
Cefadroxil
Cefamandole
Cefazolin
Cefdinir
Cefepime
Cefixime
Cefmenoxime
Cefmetazole
Cefodizime
Cefonicid
Cefoperazone
Ceforanide
Cefotaxime
Cefotetan
Cefotiam
Cefoxitin
Cefpiramide
Cefpodoxime
Cefprozil
Cefsulodin
Ceftazidime
Ceftibuten
Ceftizoxime
Ceftriaxone
Cefuroxime
Cephacetrile
Cephalexin
Cephaloglycin
Cephaloridine
Cephalothin
Cephapirin
Cephradine
Chloramphenicol
Chlortetracycline
Cilastatin
Clarithromycin
Clavulanate/clavulanic acid
Clindamycin
Clioquinol

Cloxacillin
Colistimethate
Colistin
Cyclacillin
Cycloserine
Cyclosporine
Dactinomycin
Dalfopristin
Daunorubicin
Demeclocycline
Detorubicin
Dicloxacillin
Dihydrostreptomycin
Dirithromycin
Doxorubicin
Doxycycline
Epirubicin
Erythromycin
Floxacillin
Fosfomycin
Fusidate/fusidic acid
Gentamicin
Gramicidin
Griseofulvin
Hetacillin
Idarubicin
Imipenem
Ivermectin
Kanamycin
Lincomycin
Loracarbef
Meclocycline
Meropenem
Methacycline
Methicillin
Mezlocillin
Minocycline
Mitomycin
Moxalactam
Mupirocin
Mycophenolate/mycophenolic acid
Nafcillin
Natamycin
Neomycin
Netilmicin
Niphimycin
Novobiocin
Nystatin
Oleandomycin
Oxacillin
Oxytetracycline
Paromomycin
Penicillamine
Penicillin G
Penicillin V
Phenethicillin
Piperacillin
Plicamycin
Polymyxin B
Quinupristin
Rifabutin
Rifampin
Rifamycin
Rolitetracycline
Sisomicin
Spectinomycin
Streptomycin
Streptozocin
Sulbactam
Sultamicillin
Tacrolimus
Tazobactam
Teicoplanin
Tetracycline
Ticarcillin
Tobramycin
Troleandomycin
Tyrothricin
Vancomycin
Vidarabine
Viomycin

Dated: October 5, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy

[FR Doc. 00–1536 Filed 1–21–00; 8.45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N–4955]

Amendment of Various Device Regulations to Reflect Current American Society for Testing and Materials Citations; 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 certain references in various medical device regulations. The amendments would update the references in those regulations to various standards of the American Society for Testing and Materials (ASTM) to reflect the current standards designations. 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 by April 10, 2000. If FDA receives no significant adverse comment on these various medical devices regulations within the specified comment period, the agency intends to publish in the **Federal Register** a document confirming the effective date of the final rule within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective June 7, 2000. If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule comment period.

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: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Background

The ASTM notified FDA that ASTM had been working on a project to help Federal agencies update and maintain the ASTM standards that are referenced in the Code of Federal Regulations (CFR's). Use of consensus standards such as those developed by ASTM is consistent with the purposes of the National Technology Transfer and Advancement Act of 1995, signed into law on March 7, 1996 (Public Law 104–113). As part of the ASTM project, ASTM informed FDA that many ASTM standards cited in FDA's food additive and device regulations were out-of-date and provided a list of standards with their current year designations. ASTM listed 58 different regulations which, in its opinion, needed to be updated.

FDA examined the ASTM's documentation and, upon closer examination, found that 56 of the 58 different FDA regulations identified by ASTM cited obsolete ASTM standards or that, in some cases, cited ASTM standards that had been withdrawn. Most regulations involved direct and indirect food additives, although two of the affected regulations involved medical devices. Consequently, through this rulemaking, FDA is proposing to revise the device regulations identified by ASTM that contain obsolete or withdrawn ASTM standards to reflect