ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	11	1	11	500	5,500

There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current trends, FDA anticipates that 11 petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: November 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31049 Filed 12–05–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0410]

Betty J. Pendleton; Filing of Food Additive Petition (Animal Use) Sodium Stearate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Betty J. Pendleton has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium stearate as an anticaking agent in animal feed.

DATES: Written comments on the petitioner's environmental assessment by February 4, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Henry E. Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1724.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2236) has been filed by Betty J. Pendleton, 15505 Country Ridge Dr., Chesterfield, MO 63017. The petition proposes to amend the food additive regulations in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of sodium stearate as an anticaking agent in animal feed.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before February 4, 1997, submit to the Dockets Management Branch (address above) written comments. 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. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's findings of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: November 15, 1996.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 96–31048 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96P–0090]

Determination That Testosterone Propionate 2% Ointment Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

Note: This document was originally published at 61 FR 59233, on Thursday, November 21, 1996. The document was inadvertently published with an incorrect signature. For the convenience of the reader, the document is being republished in its entirety.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that testosterone propionate 2% ointment (Perandren Ointment) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for testosterone propionate 2% ointment.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the listed drug, which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (the act)

(21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On March 19, 1996, Richard Hamer Associates, Inc., submitted a citizen petition (Docket No. 96P–0090/CP1) under 21 CFR 10.25(a), 10.30, and § 314.161(b), requesting that the agency determine whether testosterone propionate 2% ointment was withdrawn from sale for reasons of safety or effectiveness and, if the agency determines that the drug was not withdrawn from sale for reasons of safety or effectiveness, to relist the drug in the Orange Book. Testosterone propionate 2% ointment (Perandren Ointment) was the subject of approved NDA–0499 held by Ciba Pharmaceutical Co. In the Federal Register of September 23, 1971 (36 FR 18885), FDA withdrew approval of NDA– 0499 for Perandren Ointment based on the applicant's failure to submit required annual reports (section 505(e) of the act (21 U.S.C. 355(e)) and 21 CFR 314.80 and 314.81).

FDA has reviewed its records and, under §§ 314.161 and 314.162(c), has determined that testosterone propionate 2% ointment was not withdrawn from sale for reasons of safety or effectiveness and will relist testosterone propionate 2% ointment in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to testosterone propionate 2% ointment may be approved by the agency.

Dated: November 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31119 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0413]

Draft Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions for Liquid Chemical Germicides.'' The draft guidance provides specific directions to manufacturers regarding information and data that should be submitted to FDA in a premarket notification (510(k)) submission for a liquid chemical germicide. This draft guidance, dated April 26, 1995, replaces a previous version dated January 31, 1992.

DATES: Written comments by March 6, 1997.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (toll free outside of MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 2085O, 301–443–8913.

SUPPLEMENTARY INFORMATION: FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a liquid chemical germicide medical device must submit a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) to FDA before introducing the device into interstate commerce. Regulations governing the general content and format of 510(k) submissions (21 CFR part 807) and other regulatory requirements are discussed in guidance documents available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (address above). The intent of this draft guidance is to provide 510(k) applicants with specific directions regarding information and data that should be submitted to FDA in a 510(k) submission for a liquid chemical germicide medical device.

The effective use of chemical germicides is important in preventing nosocomial infections. Comprehensive, scientifically sound criteria for the evaluation of chemical germicides is essential to help ensure that these agents are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, with the agency's 510(k) submission criteria for chemical germicides in order to facilitate assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process. The draft guidance is predicated upon the legal principles of the 510(k) process. It also draws upon the longstanding regulatory and scientific basis for evaluation of germicides by the Federal government. It is a product of interactions with interested parties in industry, government, and academia as well as with infection control and other health care professionals.

This is a draft guidance document, and as such does not create or confer any rights for or on any person and does not operate to bind FDA or others; however, it does represent FDA's recommendations at this time. The draft guidance is not static and, thus, will be periodically revised to remain current with the state of the art in this fast changing area.

Interested persons may on or before March 6, 1997, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 and received comments may