preamble to today's action, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's action implements requirements specifically set forth by the Congress in Sections 4005(c)(1)(B) and (c)(1)(C) of Subtitle D of the Resource Conservation and Recovery Act (RCRA), as amended, without the exercise of any discretion by EPA. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to today's action.

Certification Under the Regulatory Flexibility Act

EPA has determined that this authorization will not have a significant adverse economic impact on a substantial number of small entities. By approving State municipal solid waste permitting programs, owners and operators of municipal solid waste landfills who are also small entities will be eligible to use the site-specific flexibility provided by Part 258 to the extent the State permit program allows such flexibility. However, since such small entities which own and/or operate municipal solid waste landfills are already subject to the requirements in 40 CFR Part 258 or are exempted from certain of these requirements, such as the groundwater monitoring and design provisions, this approval does not impose any additional burdens on these small entities.

Therefore, EPA provides the following certification under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act Pursuant to the provision at 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant adverse economic impact on a substantial number of small entities. It does not impose any new burdens on small entities; rather this approval creates flexibility for small entities in complying with the 40 CFR Part 258 requirements. Today's action, therefore, does not require a regulatory flexibility analysis.

Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) of the Administrative Procedures Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing today's document and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of today's action in the **Federal Register**. Today's action is not a ''major rule'' as defined by section 804(2) of the APA as amended.

Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (the Act), Public Law 104–4, which was signed into law on March 22, 1995, EPA generally must prepare a written statement for rules with Federal mandates that may result in estimated costs to State, local, and tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. When such a statement is required for EPA rules, under section 205 of the Act EPA must identify and consider alternatives, including the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. EPA must select that alternative, unless the Administrator explains in the final rule why it was not selected or it is inconsistent with law. Before EPA establishes regulatory requirements that may significantly or uniquely affect small governments, it must develop under section 203 of the Act a small government agency plan. The plan must provide for notifying potentially affected small governments, giving them meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising them on compliance with the regulatory requirements.

The Agency does not believe that approval of the State's program would result in estimated costs of $100 million or more to State, local, and tribal governments in the aggregate, or to the private sector, in any one year. This is due to the additional flexibility that the State can generally exercise (which will reduce, not increase, compliance costs). Thus, today's document is not subject to the written statement requirements in sections 202 and 205 of the Act.

As to section 203 of the Act, the approval of the State program will not significantly or uniquely affect small governments including Tribal small governments. As to the applicant, the State has received notice of the requirements of an approved program, has had meaningful and timely input into the development of the program requirements, and is fully informed as to compliance with the approved program. Thus, any applicable requirements of section 203 of the Act have been satisfied.

Authority: This document is issued under the authority of sections 2002, 4005 and 4010(c) of the Solid Waste Disposal Act, as amended; 42 U.S.C. 6912, 6945 and 6949(a)(c).

Dated: October 8, 1998.

Chuck Clarke,

Regional Administrator, Region 10.

[FR Doc. 98–27970 Filed 10–16–98; 8:45 am]

BILLING CODE 6560–50–U

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled ''Flood Insurance.''

DATES: Comments must be submitted on or before December 18, 1998.

ADDRESSES: Interested parties are invited to submit written comments to Tamara R. Manly, Management Analyst (Regulatory Analysis), (202) 898–7453, Office of the Executive Secretary, Room 4058, Attention: Comments/OES, Federal Deposit Insurance Corporation, 550 17th Street, NW, Washington, DC 20429. All comments should refer to ''Flood Insurance.'' Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m. (FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tamara R. Manly, at the address identified above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

Title: Flood Insurance.

OMB Number: 3064–0120.

Frequency of Response: As needed.

Affected Public: Any depository institution whose borrower's loan requests were secured by a building located on property in a special flood hazard area.

Estimated Number of Respondents: 6,000.

Estimated Time per Respondent: 25.9 hours.

Estimated Total Annual Burden: 155,625.

General Description of Collection: Each supervised lending institution is currently required to provide a notice of special flood hazards to a borrower acquiring a loan secured by a building on real property located in an area identified by the Director of the Federal Emergency Management Administration as being subject to special flood hazards. The Riegle Community Development and Regulatory Improvement Act requires that each institution must also provide a copy of the notice to the servicer of the loan (if different from the originating lender).

Request for Comment

Comment are invited on: (a) whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques of other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, DC this 13th day of October, 1998.

Federal Deposit Insurance Corporation.

Rober E. Feldman,

Executive Secretary.

[FR Doc. 98–27883 Filed 10–16–98; 8:45 am]

BILLING CODE 6714–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0086]

Determination That Sutilains Ointment USP Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that sutilains ointment USP (Travase® 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 sutilains ointment USP.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5648.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted 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 (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 (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 February 11, 1998, Hogan & Hartson, L.L.P. submitted a citizen petition (Docket No. 98P–0086/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether sutilains ointment USP was withdrawn from sale for reasons of safety or effectiveness. Sutilains ointment USP (Travase® Ointment) is the subject of NDA 12–828. FDA approved NDA 12–828, held by Travenol Laboratories, on June 12, 1969. The right to market sutilains ointment USP was subsequently transferred to Boots Pharmaceuticals, Inc., which became part of Knoll Pharmaceuticals (Knoll) on April 1, 1995. Knoll stopped distribution of the drug product effective March 29, 1996.

FDA has reviewed its records and, under § 314.161, has determined that Knoll's decision not to market sutilains ointment USP was not for reasons of safety or effectiveness. Accordingly, the agency will move sutilains ointment USP to 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 sutilains ointment USP may be approved by the agency.

Dated: October 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27889 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0864]

Privacy Act of 1974; Altered System of Records, Including Addition of Routine Use(s) to an Existing System of Records

AGENCY: Department of Health and Human Services (HHS).