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### Determination That Sutilains Ointment USP Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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