

**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]

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## **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).

**ACTION:** Notification of an altered system of records, including the addition of a new routine use.

**SUMMARY:** In accordance with the requirements of the Privacy Act of 1974 (Privacy Act), the Department of Health and Human Services (HHS) is publishing notice of a proposal to alter Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA," including the addition of a new routine use. The major purposes of the proposed alterations are to add the names of the Center for Food Safety and Applied Nutrition (CFSAN), and the Center for Veterinary Medicine (CVM), and related information regarding these Centers, to ensure that the system covers all of the Food and Drug Administration's (FDA's) Centers; update the relevant statutory and regulatory citations; and modify the routine uses section of the existing system notice by removing unnecessary routine uses, revising other routine uses to bring them in conformance with case law, and adding a new routine use providing for disclosure of covered records to sponsors and Institutional Review Boards (IRB's) involved with studies affected by a clinical investigator's violative or potentially violative conduct.

**DATES:** Submit written comments on the proposed alterations, including the new routine use, by November 18, 1998. HHS sent a Report of Altered System to the Congress and the Office of Management and Budget (OMB) on October 19, 1998. The alteration to the system of records will be effective 40 days from the date submitted to OMB unless HHS receives comments which would result in a contrary determination.

**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:** Regulatory Counsel (HFC-230), Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy, Food and Drug Administration, 12720 Twinbrook Pkwy., suite 517, Rockville, MD 20852, 301-827-0412.

**SUPPLEMENTARY INFORMATION:** FDA proposes to alter Privacy Act System of Records 09-10-0010 for the "Bioresearch Monitoring Information System, HHS/FDA." The major purposes of the proposed alterations are to: (1) Add the names of CFSAN, and CVM, and related information regarding these Centers, to ensure that the system covers all of FDA's Centers; (2) update the relevant statutory and regulatory

citations; and (3) modify the routine uses section of the existing system notice by removing unnecessary routine uses, revising other routine uses to bring them in conformance with case law, and adding a new routine use providing for disclosure of covered records to sponsors and IRB's involved with studies affected by a clinical investigator's violative or potentially violative conduct.

The records in this system will be maintained in a secure manner compatible with their content and use. All records are kept in secured areas, locked rooms, and locked buildings. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13 of the Department's General Administration Manual, and the Department's Automated Information Systems Security Handbook. Data stored in computers will be accessed through the use of regularly expiring passwords and individual ID's known only to authorized users.

FDA staff will be required to adhere to the provisions of the Privacy Act (5 U.S.C. 552a) and the HHS Privacy Act regulations (45 CFR 5b). Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are FDA employees and contractors responsible for training the individuals who will inspect the facilities of the clinical investigators, who compile and analyze the inspectional data and information, or who, as a part of their official duties, routinely disclose information under the Freedom of Information Act (FOIA) or conduct other authorized sharing of FDA records. Users will be required to sign an agreement indicating their cooperation with FDA systems security and Privacy Act policies.

The proposed alteration contains a new routine use permitting disclosure of records in the system to sponsors and IRB's associated with the clinical investigator's studies. Under the altered system, FDA may disclose to sponsors and IRB's those records that on their face, or in conjunction with other records, indicate a violation or potential violation of the law by clinical investigators that have conducted or are conducting studies. Disclosure would be made either under a request from the sponsor or IRB or, in FDA's discretion, without the need for a request. The purpose of disclosure would be to alert these parties to inspectional findings

indicating violations or potential violations of the laws enforced by FDA, including the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) and its implementing regulations. Such disclosure is compatible with the purpose of the system because the sponsors and IRB's play a significant role in ensuring that clinical investigators meet the applicable statutory and regulatory requirements. Disclosure also provides the sponsors and IRB's with information that is important to meeting their responsibilities under FDA's regulations, including their responsibility to monitor the data collected under the study.

In some cases, evidence of a violation or potential violation may implicate more than one of the clinical investigator's studies. Where more than one clinical study is involved, FDA may, where it deems appropriate, share information concerning a violation or potential violation with the sponsors and IRB's of any of the clinical investigator's studies.

In addition to creating a new routine use, the proposed alteration will delete as unnecessary two routine uses which provide for disclosure of records to certain employees of the agency for use in performance of their duties, thereby duplicating another Privacy Act exemption, 5 U.S.C. 552a(b)(1). The proposed alteration also will revise language in the remaining routine uses to bring them in conformance with recent case law. (See *Covert v. Harrington*, 876 F.2d 751 (9th Cir. 1989).) Minor editorial revisions also have been made throughout the system notice to enhance its clarity and specificity, and to accommodate normal updating changes.

Interested persons may, on or before (*insert date 30 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding the revised system notice. 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.

The following notice is written in the present, rather than the future tense, to avoid the unnecessary expenditure of public funds to republish the notice after the alteration and routine use has become effective. The revised system notice, including the proposed alterations, is set forth in full below.

Dated: October 9, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy  
Coordination.*

**Revised System Notice**

**09-10-0010**

**SYSTEM NAME:**

Bioresearch Monitoring Information System, HHS/FDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality, Bioresearch Monitoring Team (HFM-650), 1401 Rockville Pike, Rockville, MD 20852.

Center for Devices and Radiological Health (CDRH), Office of Compliance, Division of Bioresearch Monitoring (HFZ-310), 2094 Gaither Rd., Rockville, MD 20850.

Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Scientific Investigations (HFD-340), 7520 Standish Pl., Rockville, MD 20855.

Center for Food Safety and Applied Nutrition (CFSAN), Office of Premarket Approval, Division of Product Policy (HFS-205), 200 C St. SW., Washington, DC 20204.

Center for Veterinary Medicine (CVM), Office of Surveillance & Compliance (HFV-234), Division of Compliance, Bioresearch Monitoring Staff, 7500 Standish Pl., Rockville, MD 20855.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Clinical investigators who are conducting, or have conducted, clinical studies of new drugs, biologics, and devices under investigational new drug and biologics, and investigational device exemption requests; clinical investigators who are conducting, or have conducted, studies on food or color additives, generally recognized as safe (GRAS) substances, or infant formula; and clinical investigators who are conducting, or have conducted, studies on new animal drugs under investigational new animal drug requests.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Automated file is maintained on all clinical investigators; contains name, education, professional qualifications and background, Program Oriented Data Systems (PODS) locator code, and information on studies conducted. Manual file contains, in addition to that same information, investigatory material

collected by, or developed by, the Food and Drug Administration (FDA), during investigations of possible violations of statutes and regulations governing new drug, biologic, food or color additive, GRAS substance, infant formula, new animal drug, and/or device studies.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 505(i)(3), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3)), 21 CFR part 312 (new drugs and biologics for investigational use); Section 520, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), 21 CFR part 812 (new devices for investigational use); Sections 512(j) and (l)(1), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(j) and (l)(1)), 21 CFR part 511 (new animal drugs for investigational use); Sections 409 and 721, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 and 379e), 21 CFR part 71 (color additive petitions), 21 CFR part 171 (food additive petitions); Section 412, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) (infant formula requirements); and Section 351, Public Health Service Act (42 U.S.C. 262).

**PURPOSE(S):**

1. To provide controls to assure that investigators meet requirements of the relevant statutes and regulations governing new drug, biologic, food or color additive, GRAS substance, infant formula, new animal drug, and/or device studies.

2. To serve as a data base for the effective performance of activities necessary for the conduct of the bioresearch monitoring program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Records that, on their face or in conjunction with other records, indicate a violation or potential violation of law, may be: (1) Referred for investigation and possible enforcement action under the applicable Federal, State, or foreign laws to the Department of Justice and other appropriate Federal agencies, an appropriate State food and drug enforcement agency or licensing authority, or the government of a foreign country where studies are being or have been conducted; or (2) disclosed to sponsors or IRB's responsible for initiating, approving, monitoring, or overseeing any studies affected by the violation or potential violation, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutorial responsibility of the receiving entity.

2. Disclosure may be made to a congressional office from the record of

an individual in response to an inquiry from the congressional office made at the written request of that individual.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other adjudicative body, when:

(a) HHS, or any component thereof; or  
(b) Any HHS employee in his or her official capacity; or

(c) Any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or

(d) The United States or any agency thereof (where HHS determines that the litigation is likely to affect HHS or any of its components),

is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other adjudicative body, is relevant and necessary to the litigation and would help in the effective representation of the governmental interest, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files of investigatory materials are maintained in letter-size manila folders and on microfilm. Automated files are maintained on magnetic disk or tape.

**RETRIEVABILITY:**

Indexed by name or code number.

**SAFEGUARDS:**

1. *Authorized users:* Personnel in CBER's Bioresearch Monitoring Team and CBER Product Review Offices; Personnel in CDRH's Division of Bioresearch Monitoring; Personnel in CDER's Division of Scientific Investigations, Division of Drug Information Resources, Management and Data Systems Branch; Personnel in CFSAN's Division of Product Policy, Division of Health Effects Evaluation; and Personnel in CVM's Division of Compliance, Bioresearch Monitoring Staff.

2. *Physical safeguards:* Files are stored in secured areas, locked buildings, locked rooms, locked tape vaults, and lockable data media cabinets.

3. *Procedural (or technical) safeguards:* Limited access and computer password which is changed periodically.

4. *Implementation guidelines:* These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and the Department's Automated Information System Security Handbook.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the FDA Records Control Schedule transmittal number H:90–1, Departmental number B–331.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Inspections and Surveillance (HFM–650), Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, 1401 Rockville Pike, Rockville, MD 20852.

Director, Division of Bioresearch Monitoring (HFZ–310), Office of Compliance, Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

Deputy Director, Division of Scientific Investigation (HFD–341), Center for Drug Evaluation and Research, Office of Compliance, 7520 Standish Pl., Rockville, MD 20855.

Bioresearch Monitoring Project Manager (HFS–207), Center for Food Safety and Applied Nutrition, Office of Premarket Approval, Division of Product Policy, 200 C St. SW., Washington, DC 20204.

Manager, Bioresearch Monitoring Program (HFV–234), Center for Veterinary Medicine, Division of Compliance, 7500 Standish Pl., Rockville, MD 20855.

**NOTIFICATION PROCEDURES:**

An individual may learn if a record exists about him or her upon written request with notarized signature or certification of identification under penalty of perjury if request is made by mail, or with identification if request is made in person (see also 21 CFR 21.44), directed to:

FDA Privacy Act Coordinator (HFI–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the system manager. If access is denied to requested records, an appeal may be made to:

Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

You may also request an accounting of disclosures that have been made of your record, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Individual on whom the record is maintained. Some material is obtained from third parties, e.g., drug companies, publications, or is developed by FDA.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

This system is exempt from access and contest and certain other provisions of the Privacy Act (5 U.S.C. 552a(c)(3), (d)(1) to (d)(4), (e)(3), (e)(4)(G) to (e)(4)(H) and (f)) to the extent that it includes investigatory material compiled for law enforcement purposes, where access would be likely to prejudice the conduct of the investigation.

[FR Doc. 98–27937 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 97N–0135]

**Agency Information Collection Activities; Announcement of OMB Approval; OTC Test Sample Collection Systems for Drugs of Abuse Testing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "OTC Test Sample Collection Systems for Drugs of Abuse Testing" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of March 5, 1998 (63 FR 10792), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0368. The approval expires on April 30, 2001.

Dated: October 9, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–27887 Filed 10–16–98; 8:45 am]

BILLING CODE 4160–01–F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98D–0514]

**Draft Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability; Reopening of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening until November 23, 1998, the comment period for the draft guidance for industry entitled "ANDA's: Impurities in Drug Substances." FDA published a notice of availability of the draft guidance in the **Federal Register** of July 24, 1998 (63 FR 39880). FDA is taking this action in response to several requests for an extension.

**DATES:** Written comments on the draft guidance may be submitted by November 23, 1998. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of the draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>". Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft