meet with the medical gases industry before issuing any guidance.

The intent of this survey is stated above and is not applicable to the medical gases industry.

The agency does however, agree with the statement addressed in the second comment regarding the initial contact FDA makes with the 285 facilities would be more effective and save valuable resources if made by telephone. This call could determine whether the health care facility is one of those covered by this assignment and our April 6, 2001, FDA public health advisory entitled ''Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities.''

Dated: February 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–2998 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ceftiofur

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provided revised susceptibility information for food-animal pathogens listed in the clinical microbiology section of labeling for ceftiofur sodium sterile powder for injection.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed a supplement to NADA 140–338 which provides for the veterinary prescription use of NAXCEL (ceftiofur sodium) Sterile Powder for Injection. The supplemental NADA provided updated susceptibility data for food-animal pathogens listed in the clinical microbiology section of labeling. In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that this supplemental NADA is approved as of December 31, 2003. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

Dated: January 30, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–2892 Filed 2–10–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 224–04–8000]

Memorandum of Understanding Between the Food and Drug Administration and the National Library of Medicine, National Institutes of Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Library of Medicine, National Institutes of Health (NIH) to transfer an initial lot of records and arrange the future transfer of similar records on a continual basis.

DATES: The agreement became effective December 23, 2003.

FOR FURTHER INFORMATION CONTACT: John Swann, Office of Regional Operations (HF–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3756.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: February 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

224-04-8000

Memorandum of Understanding between the Food and Drug Administration and the National Library of Medicine

I. Purpose

The purpose of this agreement is to transfer an initial lot of records and arrange the future transfer of similar records on a continual basis from the Food and Drug Administration (FDA) to the National Library of Medicine, National Institutes of Health (NIH).

II. Background

This agreement is needed to ensure the preservation of and access to a collection of historically significant records. Judicial case files (formerly known as seizure case files) are the published and unpublished documentation of action taken by the Bureau of Chemistry (1907-1927), the Food, Drug, and Insecticide Administration (1927-1930), and the Food and Drug Administration (1930 to the present) against violations of the laws under the jurisdiction of FDA and its predecessor agencies; for the majority of actions, the laws in question are the 1906 Food and Drugs Act and the 1938 Food, Drug, and Cosmetic Act. Because of the increasing breadth of these laws, the judicial case files offer a unique insight into the span of the twentieth-century American marketplace--especially certain health related industries--and the consumer's place therein. Also, they shed light on the relationship between government and industry, particularly in the way manufacturers provided health care and nutrition to the public. Such a view would be difficult or impossible to achieve in any other single collection of records.

The National Archives has classified the judicial case files as temporary records in FDA's Records Control Schedule. Under provisions for the disposition of temporary records in 36 CFR 1228.60 and 36 CFR 1228.136, FDA has sought to identify a venue where these records can be cared for indefinitely and made available to the public. The National Library of Medicine has a well-known archive that has been used by researchers from around the world. The judicial case files fit in well with NLM's archival documentation strategy that, among other aims, captures the development of biomedical science and health care in America. As with its many other collections of records, NLM would be able to publicize the judicial case files to a wide audience of historians and other researchers.

III. Substance of Agreement and Responsibilities of Each Agency

This agreement binds FDA as a donor of certain of its records, and NLM as a recipient and repository of the same records. FDA agrees not to destroy any judicial case files, and to transfer all rights, responsibilities, and ownership of said records to NLM. FDA acknowledges that the copyright of all materials contained in the collection that have been prepared by Federal officials in the performance of their official duties are in

the public domain. NLM in turn agrees to apply to this collection all standard operating procedures of archival management, to utilize for this collection the same means used to publicize other collections in its archive, and to make the collection available to all interested parties under the policies in effect for administration of archival collections. NLM may transfer to another institution or dispose of any of the materials that it determines are not required by the Library. However, prior to such a transfer or disposal, NLM will notify FDA and arrange to return these materials, if so requested.

The transaction of records is to be initiated with a transfer, as soon as practicable, of one group of records consisting of 13 accession lots, covering the approximate period from 1907-1963. These records are identified below:

Records Series	WNRC Accession No.	Period Covered	Volume
Seizure/Prosec.	88-59B-2098	1907-1937	870 cu. ft. (1446 boxes; bx 1-1446)
Seizure Case	88-52A-89	1938-1940	121 cu. ft. (121 boxes; bx 1-121)
Seizure Case	88-52AA-214	1940-1944	37 cu. ft. (37 boxes; bx 1-37)
Seizure Case	88-52AB-214	1940-1944	135 cu. ft. (135 boxes; bx 52-186)
E&F Case	88-52B-214	1940-1944	191 cu ft. (191 boxes; bx 187-377)
F Seizure Case	88-52C-214	1940-1944	63 cu. ft. (81 boxes; bx 378-458)
Seizure/Prosec.	88-52D-214	1940-1944	14 cu. ft. (14 boxes; bx 38-51)
Seizure Case	88-56A-278	1945-1947	208 cu. ft. (208 boxes; bx 1-208)
MFG Card Index	88-56B-278	1907-1940	16 cu. ft. (16 boxes; bx 209-224)
Seizure Case	88-59A-2703	1947-1950	189 cu. ft. (189 boxes; bx 1-189)
Seizure Case	88-60A-554	1951-1954	186 cu. ft. (186 boxes; bx 1-186)

Seizure Case	88-63A-128	1954-1957	117 cu. ft. (117 boxes; bx 1-117)
Seizure Case	88-64A-314	[1958-1963]	100 cu. ft. (100 boxes; bx 1-100)

Subsequent transfers of records dated after 1963, though the volume of records in each transaction may vary, will occur at regular intervals, at times and places agreeable to both parties. However, no records less than 20 years old will be transferred. No later than 31 December 2005, all judicial case files up through 1970 will be transferred by FDA to NLM; no later than 31 December 2007, all judicial case files up through 1980 will be transferred by FDA to NLM; and no later than 31 December 2009, all judicial case files up through 1988 will be transferred by FDA to NLM. Thereafter, every five years FDA will transfer to NLM all judicial case files that are 21 years old or older.

IV. Name and Address of Participating Parties

A. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

B. National Library of Medicine
National Institute of Health
8600 Rockville Pike
Bethesda, Maryland 20894

V. Liaison Officers

A. Contacts for FDA

a) Seung Ja Sinatra, FDA Records Officer, Division of Management Systems, Office of Management Programs, Office of Managements Systems, Office of the Commissioner, HFA-250, Room 4B-41, 5600 Fishers Lane, Rockville, Maryland 20857, 301-827-4274 (ssinatra@oc.fda.gov)

b) John P. Swann, FDA Historian, FDA History Office, Office of Resource Management, Office of Regulatory Affairs, HFC-24, Room 12-69, 5600 Fishers Lane, Rockville, Maryland 20857, 301-827-3756 (jswann@ora.fda.gov)

B. Contacts for NLM

a) Paul H. Theerman, Head, Images and Archives, History of Medicine Division, Room 1 E-21, Building 38, National Library of Medicine,

National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-594-0975 (paul_theerman@nlm.nih.gov)

b) John Rees, Associate Curator of Manuscripts, History of Medicine Division, Room 1 E-21, Building 38, National Library of Medicine, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894, 301-496-8953 (john_rees@nlm.nih.gov)

VI. Period of Agreement

The agreement becomes effective upon signature of both parties and will continue without expiration. It may be modified by mutual consent or terminated by either party upon 120 days written notice.

APPROVED AND ACCEPTED FOR THE NATIONAL LIBRARY OF MEDICINE

By Jon G. Retzlaff

Jon G. Retzlaff
Executive Officer,
National Library of Medicine

Date 12/30/03

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

By

Jeff Weber
Associate Commissioner for Management
Office of Management
Food and Drug Administration

Date 12/23/03

[FR Doc. 04–2905 Filed 2–10–04; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0035]

Draft Guidance for Industry on the Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on a draft guidance entitled ''Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis.'' The guidance was issued in 1994 (1994 draft guidance). During the past decade, a significant body of data related to the diagnosis, prevention, and treatment of osteoporosis has been published. Much of this information is relevant to osteoporosis drug development and, in particular, relates to issues surrounding clinical trial design and duration. The agency is preparing to develop an updated draft guidance on the same topic and is seeking comment on the 1994 draft guidance.

DATES: Submit written or electronic comments on the 1994 draft guidance by April 12, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 1994 draft guidance to the Division of Drug Information (HFD–240), 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 1994 draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document

FOR FURTHER INFORMATION CONTACT: Randy Hedin, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6392.

SUPPLEMENTARY INFORMATION: