

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]

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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]

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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.

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