

Dated: February 6, 2004.

Bryant L. VanBrakle,
Secretary.

[FR Doc. 04-3001 Filed 2-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Chronic Disease Prevention and Health Promotion

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Interagency Committee on Smoking and Health: Meeting.

Time and Date: 9 a.m.–4 p.m., March 9, 2004.

Place: Howard University, Armour J. Blackburn University

Center, West Ballroom 6th and Howard Place, NW., Washington, DC 20059. Telephone: (202) 806-6100.

Status: Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpretator, or have other special needs, please notify the contact person by 4:30 p.m., no later than March 5, 2004.

Purpose: The Interagency Committee on Smoking and Health advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other Federal, State, local and private agencies and (b) establishment and maintenance of liaisons with appropriate private entities, Federal agencies, and State and local public health agencies with respect to smoking and health activities.

Matters to be Discussed: The agenda will focus on Addressing Tobacco-related

Disparities Among Population Groups/Youth with a focus on Communities of Color.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the internet at <http://www.cdc.gov/tobacco> in mid-April or from Ms. Monica L. Swann, Program Specialist, Office on Smoking and Health, 200 Independence Avenue, SW., Suite 317B, Washington, DC 20201, telephone: (202) 205-8500.

Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 5, 2004.

Alvin Hall,

Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. 04-2971 Filed 2-10-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0456]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2004.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prevention of Medical Gas Mixups at Health Care Facilities

FDA has received four reports of medical gas mixups occurring during the past 5 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mixups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mixups, to determine if further steps are warranted to ensure the safety of patients.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210/211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of October 10, 2003 (68 FR 58692), FDA published a 60-day notice requesting public comment on the information collection provisions. The agency received two

comments. One comment had specific questions regarding the requirements to register firms exporting foods from Korea. The responder of the second comment feels the agency is gathering

facts with the intent of developing and implementing future guidance that would be enforced on manufacturers, fillers, and transfillers of medical gases. This comment also requests the agency

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]

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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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