
By direction of the Commission.

Emily H. Rack, Secretary.

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BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Department of Health and Human Services (HHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following are those packages submitted to OMB since the last list was published on December 12, 1986.

Public Health Service

(Call Reports Clearance Officer on 202-245-2100 or copies of packages)

Office of the Assistant Secretary for Health

Subject: 1987 National Work Injury Followback Survey—NEW—Respondents: Individuals or households;

Health Resources and Services Administration

Subject: A National Survey of Mental Health Professionals—NEW—Respondents: Individuals or households; Small businesses or organizations

Centers for Disease Control

Subject: Dioxin Morbidity and Reproductive Study of U.S. Chemical Workers—Extension—(0202-0183) Respondents: Individuals or households

OMBDesk Officer: Bruce Artim

Health Care Financing Administration

(Call Reports Clearance Officer on 301-594-8650 for copies of package)

Subject: New York Billing Form—Existing—HCFA-234

Respondents: Businesses or other for-profit

Respondent: Hospital and Hospital Health Care Complex Cost Report—Extension—(0938-0050)—HCFA-2552-85

Respondents: Businesses or other for-profit

Food and Drug Administration

[FootNote 84F-0137]

Bernard Food Industries, Inc.; Amended Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Bernard Food Industries, Inc., to amend the food additive regulations to provide for the use of aspartame as a sweetener in ready-to-serve gelatin desserts. The previous filing notice is amended to include ready-to-serve gelatins, puddings, and fillings regardless of the setting system.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition [HFF-334], Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 18, 1984 (49 FR 21118), FDA published a notice announcing that a petition (FAP 4A3775) had been filed by Bernard Food Industries, Inc., 1125 Hartrey Ave., Evanston, IL 60204. The notice proposed to provide for the safe use of aspartame as a sweetener in ready-to-serve gelatin desserts. Subsequently, Bernard Food Industries, Inc., amended the petition to include ready-to-serve gelatin puddings, puddings, and fillings regardless of the setting system.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the impact statement is not required and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).


Richard J. Ronk,
Acting Director, Center for Food Safety and Applied Nutrition. [FR Doc. 86-28947 Filed 12-18-86; 8:45 am] BILLING CODE 4160-01-M

Monensin for Use in Goats; Availability of Data

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of target animal safety, effectiveness, tissue residue, and environmental data which may be used in support of a new animal drug application (NADA) for use of monensin in the feed of goats that are maintained in confinement. The data, contained in Public Master File (PMF) 5055, were compiled under Interregional Research Project No. 4 (IR-4), a national agriculture program for obtaining clearances for use of agricultural products for minor animal species use.

ADDRESS: Submit NADA's to the Document Control Section (HFV-16), Center for Veterinary Medicine, Food and Drug Administration, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 5000 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION: The use of monensin in feed for goats is a new animal drug use under section 201(w) of the Federal Food, Drug, and Cosmetic Act (the act) [21 U.S.C. 321(w)]. As a new animal drug, it is subject to section 512 of the act [21 U.S.C. 360b] requiring that its uses be the subject of an approved NADA.

Rutgers University, IR-4 Project, Cook College, New Brunswick, NJ 08903, has provided information to demonstrate effectiveness, safety to the target animal, tissue residue, and environmental data for use of monensin in the feed of goats that are maintained in confinement for prevention of coccidiosis caused by Eimeria crandallis, E. christenseni, and E. ninakohlyakimovae. Rutgers also provided an environmental assessment of the proposed use.

The data and information are contained in PMF 5055. Sponsors of NADA’s or supplemental NADA’s may reference without further authorization the PMF to support approval. An NADA or supplemental NADA should include, in addition to a reference to the PMF, drug labeling and other information needed for approval, such as data concerning human food safety; manufacturing methods, facilities, and controls; and information addressing the potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Adriano R. Gabuten (address above).

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21
Pursuant to the Federal Advisory Committee Act and the Health Research Extension Act of 1985, November 20, 1985 [Pub. L. 99-158, section 402(b)(6)], the Director, NIH, announces the establishment of the following committees, effective January 1, 1987:
Nursing Research Study Section
Acquired Immunodeficiency Syndrome Research Review Committee

The duration of these committees is continuing unless formally determined by the Director, NIH, that termination would be in the best public interest.


James B. Wyngaarden, Director, National Institutes of Health.

Technical Electronic Product Radiation Safety Standards Committee; Rechartering

AGENCY: Food and Drug Administration.

ACTION: Notice.


DATE: Authority for this committee will expire on December 24, 1988, unless the Commissioner formally determines that rechartering is in the public interest.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office [HFA–306], Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4555.


John M. Taylor, Associate Commissioner for Regulatory Affairs.

National Institute of Environmental Health Sciences; Superfund Hazardous Waste Worker Health and Safety Training Program Notice of Meeting

Notice is hereby given of a meeting to be held at the HH5 North Auditorium, 330 Independence Avenue, SW., Washington, DC, on January 12, 1987. The meeting will begin at 10 a.m. and end at approximately 4 p.m. or at the conclusion of public comment if prior to 4 p.m. The meeting is open to the public.

Background

Congress authorized a new program of grants in Section 126 of the Superfund and Amendments and Reauthorization Act of 1986, which permits the National Institute of Environmental Health Sciences (NIEHS) to fund both classroom and field-based programs to assure that hazardous substances workers and their supervisors have been trained to meet health protection and safety standards and regulations. Such workers include those at Superfund sites, those at the scenes of environmental emergencies at hazardous waste management facilities and those engaged in transportation of hazardous wastes. Recipients of these grants are to be non-profit organizations with demonstrated ability to reach target worker populations and demonstrated experience in implementing and operating worker health and safety training and education programs. Up to $10 million per year for fiscal years 1987–1991 has been authorized to support this grant program. These dollar amounts are budget ceilings and actual amounts will be appropriated each year consistent with the Federal budget process.

The purpose of this meeting is to describe the new worker training program assigned to NIEHS under the new Superfund Amendments and Reauthorization Act of 1986 legislation and to receive oral and written comments and suggestions regarding this new initiative. These comments will be considered by NIEHS staff in the development of a program announcement which will solicit grant applications.

Topics to be discussed in the morning session may include but are not limited to an overview of section 126(a), Superfund Amendments and Reauthorization Act of 1986 legislation, Superfund Hazardous Waste Worker Health & Safety Training Program and possible approaches, and the NIH grants process and implementation plan. Those wishing to make oral presentations on the Worker Health & Safety Training Program will be given that opportunity following the overview. These presentations must be limited to 7 minutes. Oral presentations should be supported by written documents that can be left with NIEHS staff at the meeting.

A draft program description, which will be summarized at the meeting, is described below. Written comments are encouraged and it is requested that they be received by close of business January 9, 1987. Every effort will be made to consider comments received through January 16. In order to accommodate as many people wishing to speak as possible, persons wishing to make oral presentations should contact Ms. Riley at the address below no later than January 5, 1987.

Ms. Janet Riley, Administrative Office, OD, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709

Attendance is limited only by space available. For further information regarding the meeting, please contact Mrs. Riley at the above address or telephone 919–541–7621 or FTS 629–7621. The official Government representative for this meeting will be Dr. John Dement.

Program Description

I. Background

Hazardous waste workers include workers at active and inactive treatment, storage and disposal sites, hazardous waste clean-up and remedial action sites, emergency response personnel, and workers engaged in transportation of hazardous wastes. In addition to actual site workers and supervisors, Federal, state and local personnel may be involved with site investigation, remedial action or assessment of risk.