Maritime Commission, 1100 L Street NW., Room 10220. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of the Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–002161–006

Title: Port of Seattle Terminal Agreement.
Parties:

Port of Seattle (Port)
Cargill, Inc. (Cargill)

Synopsis: The Agreement amends the basic agreement. It provides for a change in the procedure for billing dockage. It also provides that Cargill will share the dockage revenue with the Port on a 50/50 basis. Cargill will bill and collect all dockage charges from vessels using the leased premises and have the exclusive right to assess vessels a service facility charge for use of the premises.

Agreement No.: 224–010974–005

Title: Port of Oakland Terminal Agreement.
Parties:

Port of Oakland (Port)
International Transportation Service, Inc. (ITS)

Synopsis: The Agreement amends the basic agreement to provide for the Port to reimburse, out of certain wharfage revenue at the assigned facilities, ITS for its costs in making certain transtainer runway improvements to the marine terminal facilities assigned under the basic agreement.

Agreement Nos.: 224–200178–001, 224–200178–002.

Title: Port Authority of New York and New Jersey Terminal Agreement.
Parties:

Port Authority of New York and New Jersey (Port Authority)
Carco, Inc. (Carco)

Synopsis: Agreement No. 224–200178–001 amends the basic agreement for the lease of premises at the Port Authority Auto Marine Terminal to provide for the interim operation of certain terminal facilities pending completion of construction work at the leased facilities by Carco as set forth in section 5(a) of the basic agreement.

Agreement No. 224–200178–002 further amends the basic agreement to increase the amount which the Port Authority will reimburse Carco for construction costs.

By Order of the Federal Maritime Commission.

Dated: November 30, 1989.

Joseph C. Polking,
Secretary.

[FR Doc. 89–28435 Filed 12–5–89; 8:45 am]
BILLING CODE 6730–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89D–0398]

Sponsored Compounds Used in Food-Producing Animals; Guideline for the Safety Evaluation of Bound Residues From Carcinogenic Animal Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guideline, "VIII. Guideline for the Human Food Safety Evaluation of Bound Residues Derived from Carcinogenic New Animal Drugs," that describes the kinds of tests that the sponsor may conduct to establish the safety of bound residues derived from carcinogenic animal drugs. This guideline applies to human food safety, not to target animal safety. FDA invites interested persons to submit written comments on this guideline.

DATES: Written comments on the guideline may be submitted at any time. FDA will respond to comments received before February 5, 1990.

ADDRESSES: Submit written requests for single copies of "VIII. Guideline for the Human Food Safety Evaluation of Bound Residues Derived from Carcinogenic New Animal Drugs" to the Division of Chemistry (HFV–140), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on "VIII. Guideline for the Human Food Safety Evaluation of Bound Residues Derived from Carcinogenic New Animal Drugs" to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The guideline and received comments are available for public examination in the Dockets Management Branch between 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Steven D. Brynes, Center for Veterinary Medicine (HFV–144), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2841.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 31, 1987 (52 FR 49589), FDA announced the availability of a series of seven guidelines that describe the tests that a sponsor of a new animal drug may conduct to establish the safe conditions of use of the drug in food-producing animals. Although one of these guidelines, "I. Guideline for Metabolism Studies and for Selection of Residues for Toxicological Testing," discussed in general terms some considerations FDA has made with respect to bound residues, FDA had not prepared a guideline dealing specifically with the safety evaluation of bound residues derived from carcinogenic drugs.

The human food safety assessment of bound residues derived from carcinogenic animal drugs has long challenged FDA scientifically and policywise. The complex nature of bound residues, which result primarily from the reaction of a drug metabolite with cellular macromolecules, makes the usual approaches to a safety evaluation unsuitable. FDA has prepared a guideline entitled "VIII. Guideline for the Human Food Safety Evaluation of Bound Residues Derived from Carcinogenic New Animal Drugs." In this guideline FDA describes the kinds of data it will consider in evaluating the toxicological significance of bound residues derived from carcinogenic animal drugs.

This notice of availability is issued under § 10.90(b) (21 CFR 10.90(b)), which provides for use of guideline to establish procedures of general applicability that are not legal requirements but are acceptable to the agency. Sponsors may rely upon a guideline with the assurance that it represents procedures acceptable to the agency (see § 10.90). If such persons believe that alternative procedures are also applicable, a guidelines does not preclude them from pursuing the alternative procedures. Under such circumstances, however, the agency encourages sponsors to discuss the alternative procedures in advance with FDA to prevent the expenditure of money and effort for work that may later be found to be unacceptable.

This notice is issued under 21 CFR 10.85

Dated: November 28, 1989.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-28393 Filed 12-5-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0504]

Drug Export; Imodium® A-D (Loperamide HCL) Caplet, 2 mg.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that McNeil Consumer Products Co. has filed an application requesting approval for the export of the human drug Imodium® A-D (Loperamide HCL) Caplet, 2 mg. to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Mary F. Cooper, Division of Drug Labeling Compliance (HFD-313), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8073.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that McNeil Consumer Products Co., Camp Hill Rd., Ft. Washington, PA 19034, has filed an application requesting approval for the export of the drug Imodium® A-D (Loperamide HCL) Caplet, 2 mg., to Canada. This drug is indicated for use to control the symptoms of diarrhea. The application was received and filed in the Center for Drug Evaluation and Research on October 20, 1989, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. to 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by December 18, 1989, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: November 21, 1989.

Sammie R. Young,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 89-28394 Filed 12-5-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0416]

Vitarine Pharmaceuticals, Inc.; Proposal to Withdraw Approval of Abbreviated Antibiotic Drug Applications and Abbreviated New Drug Applications; Opportunity for a Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that proposed to withdraw approval of certain abbreviated antibiotic drug applications (AADA's) and abbreviated new drug applications (ANDA's) held by Vitarine Pharmaceuticals, Inc., 227-15 North Conduit Ave., Springfield Gardens, NY 11413 (54 FR 40740; October 3, 1989). The notice inadvertently omitted the words "250 mg &" in the listing for AADA 61-471. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Margaret Sharkey, Center for Drug Evaluation and Research (HFD-366), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8041.

SUPPLEMENTARY INFORMATION: In FR Doc. 89-23374, appearing at page 40740 in the **Federal Register** of Tuesday, October 3, 1989, the following correction is made: On page 40747, first column, under the heading "Proposed Action and Notice of Opportunity for Hearing", the listing for "AADA 61-471" is corrected to read "AADA 61-471; Tetracycline Hydrochloride 250 mg & 500 mg Capsules".

Dated: November 28, 1989.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 89-28395 Filed 12-5-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89F-0481]

Exxon Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Exxon Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyisobutylene and isobutylene/isoprene copolymers as components of food-contact materials sterilized with a hydrogen peroxide solution.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4176) has been filed by Exxon Chemical Co., P.O. Box 45, Linden, NJ 07036, proposing that § 178.1005 *Hydrogen peroxide solution* (21 CFR 178.1005) be amended to provide for the safe use of polyisobutylene and isobutylene/isoprene copolymers as components of food-contact materials sterilized with a hydrogen peroxide solution.

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 notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be

published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: November 28, 1989.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-28448 Filed 12-5-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83N-0193]

Second Draft Proposed Standard for the Infant Apnea Monitor; Availability; Public Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of its "Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989" to request public comment. FDA is also announcing that it is holding a public meeting to discuss the draft standard in conjunction with the Eighth Annual Conference on Apnea of Infancy to be held on January 25 to 27, 1990, Rancho Mirage, CA 92270.

DATES: Comments on the "Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989" by March 26, 1990. The public meeting will be held on January 24, 1990, from 1 p.m. to 5 p.m., in the California Room of the Gene Autry Hotel, 4200 East Palm Canyon Dr., Palm Springs, CA 92264.

ADDRESSES: Submit written requests for single copies of the "Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989" to the Operations Staff (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft standard to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft standard and any received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: E. Jane McCarthy, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of September 10, 1982 (47 FR 39816), FDA published a final rule under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) classifying the generic type of device, the breathing (ventilatory) frequency monitor (21 CFR 868.2375), into class II (performance standards). In the Federal Register of July 8, 1983 (48 FR 31392), FDA initiated a proceeding to establish for the breathing frequency monitor a performance standard under section 514 of the act (21 U.S.C. 360d). In a notice published in the Federal Register of February 26, 1986 (51 FR 6686), FDA continued the proceeding to establish a performance standard for the breathing frequency monitor, pursuant to section 514(c) of the act and 21 CFR Part 861. The notice invited any interested persons to submit an existing standard as a proposed performance standard for the device, or to submit an offer to develop such a proposed standard. In that notice, FDA limited its proceeding to those breathing frequency monitors commonly called noenatal apnea monitors, which are intended for use on infants to detect cessation of breathing.

In the Federal Register of July 1, 1986 (51 FR 23832), FDA announced that, in accordance with the provisions of section 514(e)(3) of the act and 21 CFR 861.32, FDA may, upon application (which may be made before the acceptance of the offer), agree to contribute to the accepted offeror's cost in developing a proposed standard if FDA determines that such contribution is likely to result in a more satisfactory standard that would be developed without such contribution. Subsequently, FDA allocated approximately $250,000 to contribute to the offeror's cost for the first year of effort in developing a proposed standard.

In the Federal Register of April 22, 1988 (53 FR 13296), FDA advised that a notice of grant award (cooperative agreement) had been issued to the Emergency Care Research Institute (ECRI), 5200 Butler Pike, Plymouth Meeting, PA 19462. The cooperative agreement with ECRI was completed on August 31, 1988. Because certain requirements for the infant apnea monitor were unable to be addressed in the draft document delivered to the agency, FDA proceeded to develop a proposed standard for the infant apnea monitor, using the information developed during the cooperative agreement with ECRI (21 U.S.C. 360d(f)).

In the Federal Register of January 4, 1989 (54 FR 187), FDA announced the availability of its "First Draft Proposed Standard for the Infant Apnea Monitor—October 1988," to request public comment. Under 21 CFR 861.30, FDA shall provide interested persons an opportunity to participate in the development of a standard by accepting comments, and where appropriate, holding public meetings on issues relating to development of the standard.

Accordingly, in the same notice, FDA also announced an open public meeting to discuss the draft standard. The meeting was held on January 25, 1989, in conjunction with the Seventh Annual Conference on Apnea of Infancy held in Rancho Mirage, CA 92270.

In the Federal Register of July 25, 1989 (54 FR 30951), FDA announced an open public meeting that was held on September 11 and 12, 1989, at the Crowne Plaza Holiday Inn, Rockville, MD 20852, to discuss the current sensor modalities and devices used to measure infant apnea, combinations of sensors used to detect apnea and the pathophysiological result of apnea, and the currently used test methods.

II. Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989

Based on 22 written comments received in response to the Federal Register request for comments on the first draft proposed standard and on comments and information received at the public meetings, FDA revised the first draft proposed standard. FDA is now making available for comment its "Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989."

FDA is also announcing that it will hold an open public meeting to discuss the second draft proposed standard on January 24, 1990, from 1 p.m. to 5 p.m. at the Gene Autry Hotel (address above). FDA's public meeting will be held in conjunction with the Eighth Annual Conference on Apnea of Infancy, January 25 to 27, 1990, Rancho Mirage, CA 92270.

A summary of the proceedings of the public meeting, as well as all data and information submitted voluntarily to FDA during the public meeting to discuss the draft standard will become part of the administrative record and will be available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above). After comments, data, and information are submitted at the open public meeting and in response to this request for comments on the second "Second Draft Proposed Standard for the Infant Apnea Monitor—October 1989," FDA will publish in the Federal Register a