Dated: August 5, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–20322 Filed 8–8–96; 8:45 am]

BILLING CODE 4163–18–P]

Notice of Meeting

Office of the Director, Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: Guide to Community Preventive Services (GCPS) Task Force Meeting.

Times and Dates: 8:30 a.m.–5 p.m., August 26, 1996; 8:30 a.m.–5 p.m., August 27, 1996.

Place: CDC, Building 2, Classroom 1, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 60 people.

Purpose: The mission of the Task Force is to develop and publish a Guide to Community Preventive Services, which is based on the best available scientific evidence and current expertise regarding essential public health services and what works in the delivery of those services. The primary purpose of this first meeting is to develop a shared vision for the Guide, agree on the methods to be used in its development, and to select the first topics to be included in the Guide.

Matters to be Discussed: Agenda items include: key issues for the Guide to Community Preventive Services; defining the Target Audiences and Developing a Vision for the Anticipated Uses; Nature of the Content and Format of the Guide; Applicable lessons learned from the Guidelines Project of the Council on Linkages Between Academia and Public Health Practice; Methods and Approaches to Developing the Guide to Community Preventive Services; and Proposed Approach to the Development of the GCPS.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Marguerite Pappaioanou, the GCPS Project Director at CDC and Executive Secretary to the Task Force, Office of the Director, CDC, 1600 Clifton Road, NE, M/S D–27, Atlanta, Georgia 30333, telephone 404/639–7069.

Persons interested in reserving a space for this meeting should call 404/639–7100 by close of business on August 21, 1996.

Dated: August 5, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–20320 Filed 8–8–96; 8:45 am]

BILLING CODE 4163–18–M

National Vaccine Advisory Committee (NVAC) Subcommittee on Immunization Coverage: Meeting

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 Federal advisory committee meeting.

Name: NVAC Subcommittee on Immunization Coverage.

Times and Dates: 1:30 p.m.–5:30 p.m., August 26, 1996; 8:30 a.m.–3:30 p.m., August 27, 1996.

Place: American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, Illinois 60007.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: The Subcommittee will advise and make recommendations to the full Committee on matters related to the improvement of immunization coverage rates.

Matters to be Discussed: Agenda items include presentations from CDC researchers on immunization diagnostic projects; and from the state and city immunization programs on their program operations and challenges they face. The Subcommittee will host two panels of immunization providers discussing assessments they are performing in their practices and other innovative methods of increasing immunization coverage rates.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Alison B. Johnson, Program Analyst, National Immunization Program, CDC, 1600 Clifton Road, NE, M/S E52, Atlanta, Georgia 30333, telephone 404/639–8222.

Dated: August 5, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–20321 Filed 8–8–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96N–0165]

Rhone Merieux, Inc.; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Rhone Merieux, Inc. The NADA provides for the use of Gallimycin® (erythromycin) Poultry Formula in poultry drinking water. The sponsor requested the withdrawal of approval because the animal drug product is no longer manufactured or marketed.

EFFECTIVE DATE: August 19, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., P.O. Box 459, 2116 Eighth Avenue South, Fort Dodge, IA 50501, is the sponsor of NADA 102–656, which provides for the use of Gallimycin® (erythromycin) Poultry Formula in poultry drinking water. By letter of April 17, 1996, Rhone Merieux, Inc., requested withdrawal of approval of the NADA because the animal drug product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 102–656 and all supplements and amendments thereto is hereby withdrawn, effective August 19, 1996.

Dated: July 17, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–20341 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0101]

Determination of Regulatory Review Period for Purposes of Patent Extension; CEDAX®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CEDAX® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent

Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product CEDAX® (ceftibuten dihydrate). CEDAX® is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions: Acute Bacterial Exacerbations of Chronic Bronchitis due to *Haemophilus influenzae* (including B-lactamase-producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptoccocus pneumoniae* (penicillin-susceptible strains only), Acute Bacterial Otitis Media due to *Haemophilis influenzae* (including B-lactamase producing strains), *Moraxella catarrhalis* (including B-lactamase producing strains) or *Streptococcus pyogenes*, or Pharyngitis and Tonsillitus due to *Streptococcus pyogenes*. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for CEDAX® (U.S. Patent No. 4,812,561) from Schering-Plough Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 10, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CEDAX® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CEDAX® is 2,641 days. Of this time, 1,179 days occurred during the testing phase of the regulatory review period, while 1,462 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 28, 1988. The applicant claims September 29, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 28, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357)*: December 20, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for CEDAX® (NDA 50–686) was initially submitted on December 20, 1991.

3. *The date the application was approved*: December 20, 1995. FDA has verified the applicant's claim that NDA 50–686 was approved on December 20, 1995.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 902 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 8, 1996, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 6, 1997, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–20339 Filed 8–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0154]

Determination of Regulatory Review Period for Purposes of Patent Extension; DYNABAC®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for DYNABAC® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and