(memantine hydrochloride). NAMENDA is indicated for the treatment of moderate to severe dementia of the Alzheimer's type. Subsequent to this approval, the Patent and Trademark Office received two patent term restoration applications for NAMENDA (U.S. Patent Nos. 5,061,703 and 5,614,560) from Forest Laboratories, Inc., acting as agent for Merz Pharma GmbH & Co. KGaA, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibilities for patent term restoration. In a letter dated January 26, 2007, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of NAMENDA 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 NAMENDA is 5,001 days. Of this time, 4,699 days occurred during the testing phase of the regulatory review period, while 302 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 (the act) (21 U.S.C. 355(i)) became effective*: February 7, 1990. The applicant claims October 9, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the original IND effective date was February 7, 1990, which was the date the original IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 19, 2002. FDA has verified the applicant's claim that the new drug application (NDA) (NDA 21–487) was initially submitted on December 19, 2002.

3. *The date the application was approved*: October 16, 2003. FDA has verified the applicant's claim that NDA 21–487 was approved on October 16, 2003.

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 1,250 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by August 6, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 3, 2007. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 2, 2007.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E7–10730 Filed 6–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Information Hotline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that we have revised the Advisory Committee Information Hotline (the hotline). The hotline provides the public with access to the most current information available on FDA advisory committee meetings. This notice supersedes all previously published announcements of the hotline.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Committee Management Officer (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: The hotline can be accessed by dialing 1–800–741–8138 or 301–443–0572. The advisory committee meeting information and information updates can also be accessed via FDA's advisory committee calendar at *http://www.fda.gov/oc/advisory/accalendar/2007/default.htm*.

Each advisory committee is assigned a 10–digit number. This 10–digit number will appear in each individual notice of meeting. The public can obtain information about a particular advisory committee meeting by using the committee's 10–digit number. Information on the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made. The following is a list of each advisory committee's 10–digit number to be used when accessing the hotline.

Advisory Committee	10–Digit Access Number
Office of the Commissioner	
Pediatric Advisory Committee	8732310001
Risk Communication Advisory Committee	8732112560
Science Board to the FDA	3014512603
Center for Biologics Evaluation and Research	
Allergenic Products Advisory Committee	3014512388
Blood Products Advisory Committee	3014519516

Advisory Committee	10–Digit Access Number
Cellular, Tissue & Gene Therapies Advisory Committee	3014512389
Transmissible Spongiform Encephalopathies Advisory Committee	3014512392
Vaccines and Related Biological Products Advisory Committee	3014512391
Center for Drug Evaluation and Research	
Anesthetic and Life Support Drugs Advisory Committee	3014512529
Anti-Infective Drugs Advisory Committee	3014512530
Antiviral Drugs Advisory Committee	3014512531
Arthritis Advisory Committee	3014512532
Cardiovascular and Renal Drugs Advisory Committee	3014512533
Dermatologic and Ophthalmic Drugs Advisory Committee	3014512534
Drug Safety and Risk Management Advisory Committee	3014512535
Endocrinologic and Metabolic Drugs Advisory Committee	3014512536
Gastrointestinal Drugs Advisory Committee	3014512538
Nonprescription Drugs Advisory Committee	3014512541
Oncologic Drugs Advisory Committee	3014512542
Peripheral and Central Nervous System Drugs Advisory Committee	3014512543
Pharmaceutical Science & Clinical Pharmacology, Advisory Committee for (formerly Advisory Committee for Pharmaceutical Science)	3014512539
Psychopharmacologic Drugs Advisory Committee	3014512544
Pulmonary-Allergy Drugs Advisory Committee	3014512545
Reproductive Health Drugs, Advisory Committee for	3014512537
Center for Food Safety and Applied Nutrition	
Food Advisory Committee	3014510564
Center for Devices and Radiological Health	
Device Good Manufacturing Practice Advisory Committee	3014512398
Medical Devices Advisory Committee (composed of 18 panels)	
Anesthesiology and Respiratory Therapy Devices Panel	3014512624
Circulatory System Devices Panel	3014512625
Clinical Chemistry and Clinical Toxicology Devices Panel	3014512514
Dental Products Panel	3014512518
Ear, Nose, and Throat Devices Panel	3014512522
Gastroenterology-Urology Devices Panel	3014512523
General and Plastic Surgery Devices Panel	3014512519
General Hospital and Personal Use Devices Panel	3014512520
Hematology and Pathology Devices Panel	3014512515
Immunology Devices Panel	3014512516
Medical Devices Dispute Resolution Panel	3014510232
Microbiology Devices Panel	3014512517

Advisory Committee	10–Digit Access Number
Molecular and Clinical Genetics Panel	3014510231
Neurological Devices Panel	3014512513
Obstetrics-Gynecology Devices	3014512524
Ophthalmic Devices Panel	3014512396
Orthopaedic and Rehabilitation Devices Panel	3014512521
Radiological Devices Panel	3014512526
National Mammography Quality Assurance Advisory Committee	3014512397
Technical Electronic Product Radiation Safety Standards Committee	3014512399
Center for Veterinary Medicine	
Veterinary Medicine Advisory Committee	3014512548
National Center for Toxicological Research (NCTR)	
Science Advisory Board to NCTR	3014512559

The hotline will provide the most recent information available on upcoming advisory committee meetings, guidance for making an oral presentation during the open public hearing portion of a meeting, and procedures on obtaining copies of transcripts of advisory committee meetings. Because the hotline will communicate the most current information available about any particular advisory committee meeting, this system will provide interested parties with timely and equal access to such information. The hotline should also conserve agency resources by reducing the current volume of inquiries individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 28, 2007.

Randall W. Lutter,

Associate Commissioner for Policy.

[FR Doc. E7–10738 Filed 6–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0206]

Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices.'' The guidance sets forth the agency's recommendations for ensuring the safety of refrigerated carrot juice and other low-acid refrigerated juices. The guidance is in response to six recent cases of botulism poisoning linked to refrigerated carrot juice that occurred in the United States and Canada.

DATES: This guidance is final June 5, 2007. Submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022, FAX: 301–436–2651. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2022, or e-mail: *michael.kashtock@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices.'' The purpose of the document is to provide guidance that will assist industry in processing and labeling refrigerated carrot juice and other refrigerated low-acid juices, which are subject to the pathogen reduction provisions of the Hazardous Analysis and Critical Control Point regulation for juice (21 CFR part 120) (the juice HACCP regulation), in a manner intended to provide for the safety of the juice when offered for sale by the processor and during handling by the consumer after purchase. This guidance is in response to six cases of botulism poisoning linked to refrigerated carrot juice that occurred in the United States and Canada in September and October 2006. *Clostridium botulinum* is a bacterium commonly found in soil. Botulism is a rare but serious paralytic illness caused by botulinum toxin, a nerve poison that under certain conditions is produced by *C. botulinum*. Botulism can be fatal and is considered a medical emergency. Foodborne botulism is not common in the United States.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document