administration of misoprostol. The final approved MIFEPREX labeling recommends that patients taking mifepristone take 400 micrograms of misoprostol 2 days after taking mifepristone unless a complete abortion has already been confirmed before that time. The applicant argues from these facts that the submission of the 1994 amendment represents the first time an IND for the ''approved human drug product,'' as set forth in 21 CFR 60.22(a)(1), became effective.[1]

The investigational path of a new drug is rarely straightforward. From the time of the first submission of an IND to the time, usually years later, of final approval for marketing, the course of drug investigation goes up many blind alleys and frequently takes off in new directions. Rarely, if ever, is a drug approved under precisely the same conditions (i.e., indication(s), patient population(s), dosing regimen(s), duration of treatment, use in conjunction with other drugs, etc.) for which it is initially investigated. The decision to investigate MIFEPREX in conjunction with misoprostol under certain circumstances is typical of the kind of change that can occur in the investigation of a new drug.[2]

The applicant misperceives the nature of FDA's task in this kind of proceeding, one FDA has performed hundreds of times since 1984. A determination of the regulatory review period under 35 U.S.C. 156(g)(1)(B) is straightforward and largely ministerial in nature. Our role is not to probe a drug's investigational course and determine at what point in that course emerges the ''approved human drug product.'' To do so would be to insert into a purely ministerial function an arbitrary element of uncertainty that would clearly subvert the purpose of the statute.[3]

The relevant IND became effective on June 13, 1983. That fact, upon which everyone agrees, is all that FDA need or should find in conducting the relevant portion of its regulatory review determination of MIFEPREX.[4]

Therefore, FDA has determined that the applicable regulatory review period for MIFEPREX is 6,318 days. Of this time, 4,662 days occurred during the testing phase of the regulatory review period, while 1,656 days occurred during the approval phase.

These periods of time were derived from the following dates, summarized from the January 25, 2002, notice and modified by this amendment:

1. *The date an exemption under section 505 of the act (21 U.S.C. 355) became effective*: June 13, 1983. The applicant claims August 3, 1994, as the date the IND became effective. However, for the reasons discussed previously, FDA has determined the IND effective date was June 13, 1983.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: March 18, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for MIFEPREX (NDA 20–687) was initially submitted on March 18, 1996.

3. *The date the application was approved*: September 28, 2000. FDA has verified the applicant's claim that NDA 20–687 was approved on September 28, 2000.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. In its application for patent extension, the applicant seeks 1,825 days of patent term extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension.

Dated: October 16, 2002.

Jane A. Axelrad,

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

[FR Doc. 02–27096 Filed 10–22–02; 8:45 am]

BILLING CODE 4160–01–S

[1] For purposes of part 60 (21 CFR part 60), ''human drug product'' is defined as ''the active ingredient of a new drug or human biologic product (as those terms are used in the act and the Public Health Service Act), including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.'' (See 21 CFR 60.3(b)(10).)

[2] The applicant tries to characterize MIFEPREX as mifepristone ''in combination with another active ingredient'' in an attempt to take advantage of portions of the definition of ''human drug product'' in 35 U.S.C. 156(f), that is, a human drug product means ''the active ingredient of a new drug * * * as a single entity or in combination with another active ingredient.'' The applicant points to the definition of ''combination product'' at 21 CFR 3.2(e)(3) in this effort. A more useful description of a drug ''in combination with another active ingredient'' is found at 21 CFR 300.50 (two or more drugs combined in a single dosage form). MIFEPREX is not mifepristone ''in combination with another active ingredient.'' MIFEPREX is single entity mifepristone.

[3] Indeed, using the kind of scrutiny recommended by the applicant, one could argue that the testing phase should be entirely disregarded for purposes of regulatory review period determinations because final labeling of any product, an essential element of an approved human drug product, is not established until well after the testing phase is complete.

[4] In our initial determination, we did not take into account the effect of 35 U.S.C. 156(g)(4)(C) and, instead, accepted as harmless the applicant's request for a later date.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Development of Donor Screening Assays for West Nile Virus; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Development of Screening Assays for West Nile Virus.'' The objectives of the workshop are to review current developments in West Nile Virus (WNV) transmission in the United States and to explore strategies to address issues related to the development of donor screening tests and the utility of virus inactivation methods.

Date and Time: The workshop will be held November 4 and 5, 2002, from 8 a.m. to approximately 5 p.m. on both days.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Metro Center, Bethesda, MD.

Contact Person: Joseph Wilczek, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6129, FAX 301–827–2843, e-mail: *wilczek@cber.fda.gov*.

SUPPLEMENTARY INFORMATION: FDA, Office of the Secretary/Office of Public Health and Science, the Centers for Disease Control and Prevention, the National Heart, Lung and Blood Institute at the National Institutes of Health, and the Health Resources Services Administration are co-sponsoring a public workshop to focus on scientific issues related to the development of tests that are suitable for screening blood and organ/tissue donors for WNV. The ongoing epidemic of WNV infections has raised concerns that WNV can be transmitted through blood transfusions and organ/tissue donations. Currently, there are no tests available to screen blood and organ/tissue donors for WNV nor are there data available about the stability of WNV in such tissues.

On the first day, the workshop will deal with the topics of WNV pathogenicity and epidemiology, methodologies suitable for screening WNV in blood and organ/tissue donors, and development of WNV screening assays for future large-scale implementation in a donor screening setting. On the second day, it will focus on the prospective studies for establishing the transmission to

recipients of blood, or human cells, tissues, and cellular or tissue based products, issues relevant to implementation of WNV tests, FDA's expectation for licensure of WNV tests, and strategies for inactivation.

Registration: Because seating space is limited, we recommend early registration. Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (see *Contact Person*). Registration at the site will be done on a space available basis on the days of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the transcript will be placed on the FDA Web site at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: October 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–27097 Filed 10–23–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

The President's New Freedom Commission on Mental Health; Notice of Meeting

Pursuant to Executive Order 13263, notice is hereby given of a meeting of the President's New Freedom Commission on Mental Health in November 2002.

The meeting will be open and will consider how to accomplish the Commission's mandate to conduct a comprehensive study of the United States mental health service delivery system and to make recommendations on improving the delivery of public and private mental health services for adults and children. The Commission meeting will focus on housing and homelessness, among other issues.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed as contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

Additional information and a roster of Commission members may be obtained either by accessing the Commission website, *www.mentalhealthcommission.gov*, or by communicating with the contact whose name and telephone number is listed below.

Committee Name: The President's New Freedom Commission on Mental Health.

Meeting Date/Time: Open: November 13, 2002, 9:45 a.m. to 4:30 p.m., Open: November 14, 2002, 9:30 a.m. to 12 Noon.

Place: Le Meridien Hotel, 465 S. La Cienega Boulevard, Los Angeles, California 90048.

FOR FURTHER INFORMATION CONTACT: Claire Heffernan, Executive Secretary, 5600 Fishers Lane, Parklawn Building, Room 13C–26, Rockville, MD 20857, Telephone: (301) 443–1545; Fax: (301) 480–1554 and e-mail: *Cheffern@samhsa.gov*, website: *www.mentalhealthcommission.gov.*

Dated: October 18, 2002.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 02–27049 Filed 10–23–02; 8:45 am]

BILLING CODE 4162–20–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–990 (Final)]

Non-Malleable Cast Iron Pipe Fittings From China

AGENCY: International Trade Commission.

ACTION: Scheduling of the final phase of an antidumping investigation.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping investigation No. 731–TA–990 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of less-than-fair-value imports from China of non-malleable cast iron pipe fittings, provided for in subheadings 7307.11.00 and 7307.19.30 of the Harmonized Tariff Schedule of the United States.[1]

For further information concerning the conduct of this phase of the investigation, hearing procedures, and rules of general application, consult the Commission's rules of practice and procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: September 25, 2002.

FOR FURTHER INFORMATION CONTACT: Valerie Newkirk ((202) 205–3190), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ON–LINE) at *http://dockets.usitc.gov/eol/public*.

SUPPLEMENTARY INFORMATION:

Background.—The final phase of this investigation is being scheduled as a result of an affirmative preliminary determination by the Department of Commerce that imports of non-malleable cast iron pipe fittings from China are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on February 21, 2002, by Anvil International, Inc., Portsmouth, NH, and Ward Manufacturing, Inc., Blossburg, PA.

Participation in the investigation and public service list.—Persons, including

[1] For purposes of this investigation, the Department of Commerce has defined the subject merchandise as ''finished and unfinished non-malleable cast iron pipe fittings with an inside diameter ranging from ¼ inch to 6 inches, whether threaded or un-threaded, regardless of industry or proprietary specifications. The subject fittings include elbows, ells, tees, crosses, and reducers as well as flanged fittings. These pipe fittings are also known as cast iron pipe fittings or gray iron pipe fittings. These cast iron pipe fittings are normally produced to ASTM A–126 and ASME B.16.4 specifications and are threaded to ASME B1.20.1 specifications. Most building codes require that these products are Underwriters Laboratories (UL) certified. The scope does not include cast iron soil pipe fittings or grooved fittings or grooved couplings.

Fittings that are made out of ductile iron that have the same physical characteristics as the gray or cast iron fittings subject to the scope above or which have the same physical characteristics and are produced to ASME B.16.3, ASME B.16.4, or ASTM A–395 specifications, threaded to ASME B1.20.1 specifications and UL certified, regardless of metallurgical differences between gray and ductile iron, are also included in the scope. These ductile fittings do not include grooved fittings or grooved couplings. Ductile cast iron fittings with mechanical joint ends (MJ), or push on ends (PO), or flanged ends and produced to American Water Works Associations (AWWA) specifications AWWA C110 or AWWA C153 are not included.''