

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**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 Femara® (letrozole). Femara® is indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration

application for Femara® (U.S. Patent No. 4,978,672) from Novartis 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 December 16, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Femara® 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 Femara® is 2,160 days. Of this time, 1,794 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* August 28, 1991. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 28, 1991.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* July 25, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Femara® (NDA 20-726) was initially submitted on July 25, 1996.

3. *The date the application was approved:* July 25, 1997. FDA has verified the applicant's claim that NDA 20-726 was approved on July 25, 1997.

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 1,232 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 9, 1999, 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 November 8, 1999, 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: April 29, 1999.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 99-11584 Filed 5-7-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0487]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Denavir™

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Denavir™ 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**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 Denavir™ (Penciclovir). Denavir™ is indicated for the treatment of recurrent herpes labialis (cold sores) in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Denavir™ (U.S. Patent No. 5,075,445) from Beecham Group p.l.c., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 28, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Denavir™ 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 Denavir™ is 1,299 days. Of this time, 954 days occurred during the testing phase of the regulatory review period, 345 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* March 7, 1993. The applicant claims March 5, 1993, as the date the investigational new drug application (IND) became effective.

However, FDA records indicate that the IND effective date was March 7, 1993, 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 505 of the act:* October 16, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for Denavir™ (NDA 20-629) was initially submitted on October 16, 1995.

3. *The date the application was approved:* September 24, 1996. FDA has verified the applicant's claim that NDA 20-629 was approved on September 24, 1996.

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 640 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 9, 1999, 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 November 8, 1999, 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: April 29, 1999.

**Thomas J. McGinnis,**

*Deputy Associate Commissioner for Health Affairs.*

[FR Doc. 99-11585 Filed 5-7-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Airline Catering Workshop on Sanitation, HACCP and the 1999 Food Code; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

The Food and Drug Administration (FDA), in cooperation with the International Inflight Food Service Association, is announcing the following workshop: Airline Catering Workshop on Sanitation, HACCP and the 1999 Food Code. The workshop will discuss issues on sanitation, Hazard Analysis Critical Control Point and the 1999 Food Code.

*Date and Time:* The workshop will be held on Wednesday, June 2, 1999, 8:30 a.m. to 5 p.m.

*Location:* The workshop will be held at the Marriott Hotel, 1500 Convention Center Dr., Arlington, TX 76011, 817-261-8200.

*Contact:* Martha S. Baldwin, Dallas District, Food and Drug Administration, 3310 Live Oak St., Dallas, TX 75204, 214-655-5310, ext. 544, FAX 214-655-5200, e-mail "mbaldwin@ora.fda.gov".

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by May 26, 1999.

If you need special accommodations due to a disability, please contact Martha S. Baldwin at least 7 days in advance.

Dated: May 4, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

[FR Doc. 99-11736 Filed 5-7-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97D-0228]

#### Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled