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 Gabitril (tiagabine hydrochloride). Gabitril is indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Gabitril (U.S. Patent No. 5,010,090) from Novo Nordisk A/S, 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 26, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Gabitril represented the first permitted commercial marketing or use of the product. Subsequently, 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 Gabitril is 2,346 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 695 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*: May 1, 1991. The applicant claims May 8, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 1, 1991, 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(b) of the act*: November 6, 1995. The applicant claims November 3, 1995, as the date the new drug application (NDA) for Gabitril (NDA 20–646) was initially submitted. However, FDA records indicate that NDA 20–646 was submitted on November 6, 1995.

3. *The date the application was approved*: September 30, 1997. FDA has verified the applicant's claim that NDA 20–646 was approved on September 30, 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 1,255 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by September 10, 2001. 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 January 7, 2002. 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. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 2001.

Jane A. Axelrad,

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

[FR Doc. 01–17103 Filed 7–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0838]

Determination of Regulatory Review Period for Purposes of Patent Extension; Detrol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Detrol 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 that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 Detrol (tolterodine tartrate). Detrol is indicated

for overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Detrol (U.S. Patent No. 5,382,600) from Pharmacia & Upjohn Atiebolag, 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 11, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Detrol 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 Detrol is 1,267 days. Of this time, 901 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(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: October 7, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 7, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* March 25, 1997. The applicant claims March 24, 1997, as the date the new drug application (NDA) for Detrol (NDA 20–771) was initially submitted. However, FDA records indicate that NDA 20–771 was submitted on March 25, 1997.

3. *The date the application was approved*: March 25, 1998. FDA has verified the applicant's claim that NDA 20–771 was approved on March 25, 1998.

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 64 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by September 10, 2001. 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 January 7, 2002. 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. Three copies of any 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 11, 2001.

Jane A. Axelrad,

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

[FR Doc. 01–17105 Filed 7–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Draft Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues'' (the draft guidance). The draft guidance presents FDA's policy for implementing the channels of trade provision for the pesticide chemical vinclozolin in the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996. The draft guidance is intended to assist firms in understanding FDA's planned approach to the enforcement of this provision of the FQPA with regard to residues of vinclozolin in food.

DATES: Submit written comments concerning on the draft guidance by September 10, 2001, to ensure their adequate consideration of the comments in the preparation of a revised guidance, if warranted. However, you may submit comments at any time.

ADDRESSES: Submit written comments concerning the draft guidance and the collection of information provisions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Channels of Trade Policy for Commodities With Vinclozolin Residues'' to Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681, FAX 202–205–4422, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On August 3, 1996, the FQPA was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FFDCA, established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. In accordance with the FQPA, the Environmental Protection Agency (EPA), is responsible for regulating the use of pesticides (under the FIFRA) and establishing tolerances or exemptions from the requirement for tolerances for residues of pesticide chemicals in food commodities (under the FFDCA). EPA, in accordance with the FQPA, is in the process of reassessing the pesticide tolerances and exemptions that were in effect when the FQPA was signed into law. When EPA determines that a pesticide's tolerance level does not meet the safety standard under section 408 of the act (21 U.S.C. 346a), the registration for the pesticide may be canceled under the FIFRA for all or certain uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the FFDCA (21 U.S.C. 346a(l)(2)), when the registration for a pesticide is canceled or