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 Director 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 LEVULAN KERASTICK (aminolevulinic acid HCl). THE LEVULAN KERASTICK for topical solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of nonhyperkeratotic actinic keratoses of the face or scalp. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for LEVULAN KERASTICK (U.S. Patent No. 5,079,262) from DUSA Pharmaceuticals, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LEVULAN KERASTICK represented the first permitted commercial marketing or use of the product. 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 LEVULAN KERASTICK is 2,528 days. Of this time, 2,007 days occurred during the testing phase of the regulatory review period, while 521 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*: January 2, 1993. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 2, 1993.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: July 1, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for LEVULAN KERASTICK (NDA 20–965) was initially submitted on July 1, 1998.

3. *The date the application was approved*: December 3, 1999. FDA has verified the applicant's claim that NDA 20–965 was approved on December 3, 1999.

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 1,524 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 2, 2003. 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 September 29, 2003. 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: February 7, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–7711 Filed 3–31–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0014]

Draft Guidance on Human Subject Protection; HHS Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation of comments by HHS.

SUMMARY: The Food and Drug Administration (FDA) is announcing that in the issue of the **Federal Register** published March 31, 2003, the Department of Health and Human Services, Office of the Secretary, Office of Health and Science is soliciting public comment on a draft guidance document for Institutional Review Boards, investigators, research institutions, and other interested parties, entitled ''Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection.'' This draft guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This draft guidance applies to human subjects research conducted or supported by HHS or regulated by FDA.

DATES: HHS is accepting written or electronic comments on the draft guidance until 4:30 p.m. on May 30, 2003.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–7957 Filed 3–28–03; 2:22 pm]

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