telephone (404) 639–6270; facsimile (404) 639–6266.

A. CDC, NIOSH Is Offering

1. Exclusive use of the NIOSHTIC® Database name in relation to the production of the database: The Licensee will have unlimited use of the NIOSHTIC® Trademark for product identification and promotion.

2. Control of the current NIOSHTIC® Database master file: NIOSH will provide the Licensee with a copy of the NIOSHTIC® Database master file as it currently exists. The Licensee may reformat the data, and add or delete fields, provided that the integrity of the file is maintained or enhanced.

3. The authority and responsibility to the licensee to negotiate future agreements with all vendors, and entitlement to collect fees to maintain the database: Licensee will have the option to use existing vendor agreements until they expire, or to terminate (i.e., after a 90-day notice) existing agreements and establish new agreements.

4. An electronic copy of all NIOSH materials generated for the NIOSHTIC–2 database: NIOSH will provide an electronic copy of all citations created for the NIOSHTIC–2 database. These data will be provided in the NIOSHTIC–2 format which is considerably different from the current NIOSHTIC® Database format. The Licensee will be responsible for reformatting the material for inclusion in NIOSHTIC® Database if desired. NIOSHTIC–2 citations will consist of a wide variety of publication types including NIOSH published documents, unpublished NIOSH reports, journal articles, book chapters, etc. Only research reports conducted or funded by NIOSH will be included in NIOSHTIC–2. We anticipate that approximately 600 citations will be added to NIOSHTIC–2 annually.

5. NIOSH staff to provide counsel to Licensee: As modifications of the scope of the NIOSHTIC® Database are considered, NIOSH will provide historical perspective of the interpretations of the current Document Selection Criteria and the Core Journal List as well as all other aspects of the project.

B. NIOSH Expects the Licensee to

1. Maintain NIOSHTIC® Database as an active, viable occupational safety and health database: The Licensee must not radically alter the scope of the NIOSHTIC® Database, but modification of the current Document Selection Criteria and Core Journal List is acceptable and expected as the needs of the users dictate.

2. Market NIOSHTIC® Database so that it is available to the international occupational safety and health community: The Licensee must make NIOSHTIC® Database available world-wide in a variety of forms such as on-line, CD–ROM, and/or the Internet using the NIOSHTIC® Trademark.

3. Provide multiple point, free, and unlimited access to NIOSH employees for all products resulting from this licensing agreement: NIOSH research and information staff must have access to what will remain the world's largest and most comprehensive bibliographic database of occupational safety and health information.

4. Allow NIOSH representation on any editorial or policy board for the database: A NIOSH representation should serve on any editorial or policy board established for the NIOSHTIC® Database to ensure that the Institute's interests are considered.

5. Provide sufficient royalties to cover NIOSH's expenses for meeting travel, orientation to the product, consultation on policy issues or oversight activity as desired by either party: NIOSH believes that the overwhelming majority of revenue generated should be reinvested in the development and maintenance of the NIOSHTIC® Database and related projects.

Dated: October 8, 1998.

Thena M. Durham,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention.

[FR Doc. 98–27641 Filed 10–14–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0270]

Determination of Regulatory Review Period for Purposes of Patent Extension; Aldara™ (4,689,338)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Aldara™ (4,689,338) 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 Aldara™ (4,689,338) (imiquimod). Aldara™ (4,689,338) is indicated for the treatment of external genital and perianal warts/condyloma acuminata in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aldara™ (4,689,338) (U.S. Patent No. 4,689,338) from Riker Laboratories, 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 July 22, 1997, FDA advised the Patent

and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aldara™ (4,689,338) 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 Aldara™ (4,689,338) is 3,471 days. Of this time, 3,254 days occurred during the testing phase of the regulatory review period, 217 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 30, 1987. The applicant claims September 1, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1987, 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*: July 26, 1996. The applicant claims July 25, 1996, as the date the new drug application (NDA) for Aldara™ (4,689,338) (NDA 20–723) was initially submitted. However, FDA records indicate that NDA 20–723 was submitted on July 26, 1996.

3. *The date the application was approved*: February 27, 1997. FDA has verified the applicant's claim that NDA 20–723 was approved on February 27, 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 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 14, 1998, 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 April 13, 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: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27584 Filed 10–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0834]

Draft Guidance for Industry on Non-Contraceptive Estrogen Class Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Non-Contraceptive Estrogen Drug Products—Physician and Patient Labeling.'' The draft guidance is intended to serve as a template for sponsors of estrogen class drug products to ensure that such products contain uniform physician and patient labeling information. Once finalized, this draft guidance will replace the ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and ''Labeling Guidance for Estrogen Drug Products, Patient Package Insert,'' both of which were revised and published in August 1992.

DATES: Written comments on the draft guidance document may be submitted by December 14, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of ''Labeling Guidance for Estrogen Drug Products; Physician and Patient labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John C. Markow, Reproductive and Urologic Drug Products, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4260.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Non-Contraceptive Estrogen Drug Products; Physician and Patient Labeling.'' Once it has been finalized, the guidance will replace two existing guidance documents: (1) ''Labeling Guidance for Estrogen Drug Products, Physician Labeling'' and (2) ''Labeling Guidance for Estrogen Drug Products, Patient Package Insert,'' both of which were revised and published in August 1992. The draft guidance provides a template for both physician and patient labeling for estrogen class drug products, which sponsors should use with new drug applications and abbreviated new drug applications.

The draft guidance outlines the recommended language for the physician insert and the patient package insert. Included are black box warnings explaining the increased risk of cancer of the uterus associated with the use of estrogens. Once finalized, the recommendations in this draft guidance should be followed for all approved, pending, and future applications.

This draft guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on estrogen class labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments 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. The draft guidance and