TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
99.201(a)(5)	52	1.7	89	1	89
99.201(b)	172	1.7	297	0.5	148.5
99.201(c)	172	1.7	297	0.5	148.5
99.203(a)	1	1	1	10	10
99.203(b)	1	1	1	10	10
99.203(c)	2	1	2	0.5	1
99.205(b)	17	1.8	30	82	2,460
99.501(b)(1)	172	3.4	594	8	4,752
99.501(b)(2)	172	3.4	594	1	594
99.501(b)(3)	172	3.4	594	20	11,880
99.501(b)(4)	2	1.7	3	2	6
99.501(b)(5)	17	1.8	30	41	1,230
Total Hours					48,644

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
99.501(a)(1)	172	1.7	297	10	2,970
99.501(a)(2)	172	1.7	297	1	297
99.501(c)	172	1.7	297	1	297
Total Hours					3,564

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated burden associated with the information collection requirements for this rule is 52,208 hours.

Dated: February 26, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5387 Filed 3–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0841]

Determination of Regulatory Review Period for Purposes of Patent Extension; Regranex® and Becaplermin Concentrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Regranex® and Becaplermin Concentrate 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 those human biological products.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological products Regranex® and Becaplermin Concentrate (becaplermin). Regranex® is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Regranex® and Becaplermin Concentrate (U.S. Patent No. 4,845,075) from ZymoGenetics, 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 January 29, 1999, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Regranex® and Becaplermin Concentrate 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 Regranex® and Becaplermin Concentrate is 2,790 days. Of this time, 2,424 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*: April 29, 1990. The applicant claims March 30, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 29, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 505 of the act*: December 16, 1996. FDA has verified the applicant's claim that the product license applications (PLA's) for Regranex® (PLA 96–1408) and Becaplermin Concentrate (PLA 96–1422) were initially submitted on December 16, 1996.

3. *The date the application was approved*: December 16, 1997. FDA has verified the applicant's claim that PLA 96–1408 and PLA 96–1422 were approved on December 16, 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 1,593 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 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 August 31, 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: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–5388 Filed 3–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 1999. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the **Federal Register**. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for 1999.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4820.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report, the IOM recommended that FDA adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**. FDA has implemented this recommendation. A tentative schedule of forthcoming meetings will be published annually in the **Federal Register**. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. The schedule is tentative and amendments to this notice will not be published in the **Federal Register**. FDA will, however, publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 1999:

Committee Name	Dates of Meetings	Information Line Code
OFFICE OF THE COMMISSIONER		
Science Board to the Food and Drug Administration	June 11 September 14	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	February 22 October 26	12388
Biological Response Modifiers Advisory Committee	March 18–19 July 15–16 November 18–19	12389