of child care. A sample of low-income families using non-parental child care will be asked about the types and cost of care used and the factors that influenced their choice of child care arrangements including the availability of child care subsidies. A sample of low-income parents using family child care will be asked about their experience with this care and how this care has affected their ability to work and to balance work and family life. Additionally, parents will be asked about their household characteristics on a voluntary basis. The family child care providers used by the sample of low-income parents will be asked about their views on child rearing and the role of the child care provider, the relationship with the parents served, and on a voluntary basis, their household characteristics. A sample of children using family child care will be observed in their child care setting. Focus groups with family child care providers and low-income parents will be used to investigate how child care subsidy policy has affected the supply and demand for child care in their communities.

ACF, working with Abt Associates and the National Center for Children in Poverty at Columbia University, will conduct the proposed data collection. Data will be collected at the three levels, with nested samples of counties within states and families and providers within counties. The first level is a sample of 17 states containing 25 counties that were selected to be a nationally-representative sample of counties with above average poverty rates. At the family level, data will be collected from two samples:

X A random sample of 5,000 low-income families with working parents and at least one child under age 13 for whom they use non-parental child care, that will be selected in the 25 counties (200/county). This sample will be used to investigate the spectrum of child care options available to and the choices made by low-income families in the 25 counties.

X A sample of 650 low-income parents who are receiving, or who are eligible for, child care subsides, and are using family child care at the start of the study will be used to examine the experiences of low-income families with this important but rarely studied mode of child care. A random sample (130 families/county) will be selected from subsidy lists and, in the case of unsubsidized families, through snowball sampling in a subsample of five of the 25 counties.

At the provider level, data will be collected from the 650 family child care providers linked to these 650 families.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Key Informant Interviews	170	2	1.00	114
Community Key Informant Interviews	250	.67	1.00	168
Community Survey (Screener)	64,474	.33	0.08	1,702
Community Survey	5,000	.33	.5	825
In-Depth Study Parent Screener	2,172	.33	0.08	57
In-Depth Study Parent Interview	650	2	1.25	1,625
In-Depth Study Student Interview	63	1	.033	21
In-Depth Study Family Child Care Provider Screener	1,458	.33	.17	82
In-Depth Study Family Care In-Depth Study Care Provider Interview	650	2	.50	65

Estimated Total Annual Burden Hours: 5,244.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW, Washington, DC 20503, Attn: Stuart Schapiro.

Dated: February 26, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–5303 Filed 3–3–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0222]

Agency Information Collection Activities: Proposed Collection; Comment Request; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements associated with the dissemination of unapproved or new uses for marketed drugs, biologics, and devices.

DATES: Submit written comments on the collection of information by May 3, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration,

5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520) Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices (OMB Control Number 0910–0390)—Extension

Description: In the **Federal Register** of November 20, 1998 (63 FR 64555), FDA published a final rule to add a new part 99 (21 CFR part 99) entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.''

The final rule implemented section 401 of the Food and Drug Administration Modernization Act (FDAMA) (Pub. L. 105–115). In brief, section 401 of FDAMA amended the act to permit drug, biologic, and device manufacturers to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State Government agencies, provided that the manufacturer complies with certain statutory requirements. For example, the information that is to be disseminated must be about a drug or device that is being legally marketed; it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication; and it must not be derived from another manufacturer's clinical research, unless that other manufacturer has given its permission for the dissemination. The information must be accompanied by certain information, including a prominently displayed statement that the information discusses a use or uses that have not been approved or cleared by FDA. Additionally, 60 days before dissemination, the manufacturer must submit to FDA a copy of the information to be disseminated and any other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to the safety of the new use, and a summary of such information.

The rule sets forth the criteria and procedures for making such submissions to FDA. Under the rule, a submission would include a certification that the manufacturer has completed clinical studies necessary to submit a supplemental application to FDA for the new use and will submit the supplemental application within 6 months after its initial dissemination of information. If the manufacturer has planned, but not completed, such studies, the submission would include proposed protocols and a schedule for conducting the studies, as well as a certification that the manufacturer will complete the clinical studies and submit a supplemental application no later than 36 months after its initial dissemination of information. The rule also permits manufacturers to request extensions of the time period for completing a study and submitting a supplemental application and to request an exemption from the requirement to submit a supplemental application. The rule prescribes the timeframe within which the manufacturer shall maintain records that would enable it to take corrective action. The rule requires the manufacturer to submit lists pertaining to the disseminated articles and reference publications and the categories of persons (or individuals) receiving the information and to submit a notice and summary of any additional research or data (and a copy of the data) relating to the product's safety or effectiveness for the new use. The rule requires the manufacturer to maintain a copy of the information, lists, records, and reports for 3 years after it has ceased dissemination of the information and to make the documents available to FDA for inspection and copying.

FDA based its estimates of the number of submissions it would receive and the number of manufacturers who would be subject to part 99 on the number of efficacy and new use supplements for approved drugs, biologics, and devices received in fiscal year (FY) 1997 and on a projected increase in supplements due to FDAMA. In FY 1997, FDA received 198 efficacy and new use supplements from 115 manufacturers. The number of supplements increased 100 percent from FY 1995 to FY 1997 as a result of two new initiatives, the Prescription Drug User Fee Act and a new pediatric labeling regulation. If FDAMA results in an additional 50 percent increase in the number of supplements and a corresponding increase in the number of manufacturers, then the estimated number of submissions under part 99 is 297 (198 + (0.5 x 198)), and the estimated number of manufacturers is 172 (115 + (0.5 x 115)). These figures are reflected in Tables 1 and 2 of this document for §§ 99.201(a)(1), 99.201(a)(2), 99.201(a)(3), 99.201(b), 99.201(c), 99.501(a)(1), 99.501(a)(2), 99.501(b)(1), 99.501(b)(3), and 99.501(c).

The estimated burden hours for these provisions follow.

Section 99.201(a)(1) requires the manufacturer to provide an identical copy of the information to be disseminated, including any required information. Because the manufacturer must compile this information in order to prepare its submission to FDA, FDA estimates that 40 hours would be required per submission. Because 297 annual responses are expected under § 99.201(a)(1), the total burden for this provision is 11,880 hours (297 responses x 40 hours per response).

Section 99.201(a)(2) requires the manufacturer to submit clinical trial information pertaining to the safety and effectiveness of the new use, clinical experience reports on the safety of the new use, and a summary of the information. FDA estimates 24 burden hours per response for this provision for

assembling, reviewing, and submitting the information and assumes that the manufacturer will have already acquired some of this information in order to decide whether to disseminate information on an unapproved use under part 99. The total burden for this provision is 7,128 hours (297 annual responses x 24 hours per response).

Section 99.201(a)(3) requires the manufacturer to explain its search strategy when assembling its bibliography. FDA estimates that only 1 hour would be required for the explanation because the manufacturer would have developed and used its search strategy before preparing the bibliography. Because 297 annual responses are expected under § 99.201(a)(3), the total burden for this provision is 297 hours (297 annual responses x 1 hour per response).

Section 99.201(b) simply requires the manufacturer's attorney, agent, or other authorized official to sign its submissions, certifications, and requests for an exemption. FDA estimates that only 30 minutes are necessary for such signatures. Because 297 annual responses are expected under § 99.201(b), the total burden for this provision is 148.5 hours (297 response x 0.5 hours per response = 148.5 hours).

Section 99.201(c) requires the manufacturer to provide two copies with its original submission. FDA does not expect that copying the submission will be time-consuming and estimates the burden to be 30 minutes. Because 297 annual responses are expected under § 99.201(c), the total burden for this provision is 148.5 hours.

Yet, while FDAMA requires manufacturers to provide a submission to FDA before they disseminate information on unapproved/new uses, it also permits manufacturers to: (1) Have completed studies and promise to submit a supplemental application for the new use within 6 months after the date of initial dissemination; (2) provide protocols and a schedule for completing studies and submitting a supplemental application for the new use within 36 months after the date of initial dissemination; (3) have completed studies and have submitted a supplemental application for the new use; or (4) request an exemption from the requirement to submit a supplemental application. These possible scenarios are addressed in §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), 99.201(a)(5), and 99.205(b) respectively.

To determine the number of responses in §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), 99.201(a)(5), and 99.205(b), FDA began by estimating the number of requests for an exemption under § 99.205(b). The legislative history indicates that such exemptions are to be limited. In the final rule, FDA estimated that approximately 10 percent of all respondents would seek—or 10 percent of all submissions would contain—an ''economically prohibitive'' exemption (resulting in 17 total respondents and approximately 30 annual responses) and that the estimated reporting burden per response would be 82 hours. This results in a total hour burden of 2,460 hours for § 99.205(b) (30 submissions x 82 hours per submission).

The estimated increase in the number of exemption requests results in a corresponding decrease in the remaining number of respondents and submissions under §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), and 99.201(a)(5). FDA assumes that the remaining 267 submissions (297 total submissions—30 submissions containing an exemption request) will be divided equally among §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), and 99.201(a)(5), resulting in 89 responses in each provision (267 submissions/3 provisions). FDA has estimated the number of respondents in a similar fashion ((172 total respondents—17 respondents submitting an exemption request)/3 provisions = 51.6, rounded up to 52 respondents per provision).

As stated earlier, § 99.201(a)(4)(i)(A)) requires the manufacturer, if the manufacturer has completed studies needed for the submission of a supplemental application for the new use, to submit the protocol(s) for the completed studies, or, if the protocol was submitted to an investigational new drug application (IND) or investigational device exemption (IDE), to submit the IND or IDE number(s), the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s) must be submitted with the application. FDA estimates that 30 hours would be required for this response because this is information that each manufacturer already maintains for its drugs or devices. The total burden for this provision is 2,670 hours (89 annual responses x 30 hours per response).

For manufacturers who submit protocols and a schedule for conducting studies, § 99.201(a)(4)(ii)(A)) requires the manufacturer to include, in its schedule, the projected dates on which the manufacturer expects the principal study events to occur. FDA estimates a manufacturer would need approximately 60 hours to include the projected dates because it would have to contact the studies' principal investigator(s) and other company officials. The total burden for this provision is 5,340 hours (89 annual responses x 60 hours per response).

If the manufacturer has submitted a supplemental application for the new use, § 99.201(a)(5) requires a cross-reference to that supplemental application. FDA estimates that only 1 hour would be needed because manufacturers already maintain this information. The total burden for this provision is 89 hours (89 annual responses x 1 hour per response).

Under § 99.203, a manufacturer who has certified that it will complete studies necessary to submit a supplemental application within 36 months after its submission to FDA, but later finds that it will be unable to complete such studies or submit a supplemental application within that time period, may request an extension of time from FDA. Such requests for extension should be limited, occurring less than 1 percent of the time, because manufacturers and FDA, when developing or reviewing study protocols, should be able to identify when a study will require more than 36 months to complete. Section 99.203 contemplates extension requests under two different scenarios. Under § 99.203(a), a manufacturer may make an extension request *before* it makes a submission to FDA regarding the dissemination of information under part 99. The agency expects such requests to be limited, occurring less than 1 percent of the time (or 1 annual response), and that such requests will result in a reporting burden of 10 hours per request. The total burden hours for this provision, therefore, is 10 hours (1 annual response x 10 hours per response).

Section 99.203(b) specifies the contents of a request to extend the time for completing planned studies *after* the manufacturer has provided its submission to FDA. The required information includes a description of the studies, the current status of the studies, reasons why the study cannot be completed on time, and an estimate of the additional time needed. FDA estimates that 10 hours for reporting the required information under § 99.203(b) because it would require consultation between the manufacturer and key individuals (such as the study's principal investigator(s)). As in the case of § 99.203(a), the expected number of responses is very small (1 annual response), and the total burden hours for this provision is 10 hours (1 annual response x 10 hours per response).

Section 99.203(c) requires two copies of an extension request (in addition to the request required under section

554(c)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa–3(c)(3))), and FDA estimates that these copies would result in a minimal reporting burden of 30 minutes. However, this requirement would apply to extension requests under § 99.203(a) and (b), so the total number of annual responses is 2, resulting in a total burden hour for this provision of 1 hour (2 annual responses x 0.5 hours per response).

The remaining reporting and recordkeeping burdens follow.

Section 99.501(a)(1) requires the manufacturer to maintain records that identify recipients by category or individually. Under § 99.301(a)(3), FDA will notify the manufacturer whether it needs to maintain records identifying individual recipients due to special safety considerations associated with the new use. This means that, in most cases, the manufacturer will only have to maintain records identifying recipients by category. In either event, the manufacturer will know whether it must maintain records that identify individual recipients before it begins disseminating information. The time required to identify recipients individually should be minimal, and the time required to identify recipients by category should be even less. Therefore, FDA estimates the burden for this provision to be 10 hours, and, because 297 annual responses are expected under § 99.501(a)(1), the total burden for this provision is 2,970 hours (297 annual responses x 10 hours per response).

Section 99.501(a)(2) requires the manufacturer to maintain a copy of the information it disseminates. This task is not expected to be time-consuming, so FDA estimates the burden to be 1 hour. Because 297 annual responses are expected under § 99.501(a)(2), the total burden for this provision is 297 hours (297 annual responses x 1 hour per response).

Section 99.501(b)(1) requires the manufacturer to submit to FDA semiannually a list containing the articles and reference publications that were disseminated in the preceding 6-month period. FDA tentatively estimates a burden of 8 hours for this provision. The actual burden may be less if the manufacturer develops and updates the list while it disseminates articles and reference publications during the 6-month period (as opposed to generating a completely new list at the end of each 6-month period) and if the volume of disseminated materials is small. The total burden for this provision is 4,752 hours (297 responses submitted semiannually x 8 hours per response = 297 x 2 x 8 = 4,752 hours).

Section 553(a)(2) of the act (21 U.S.C. 360aaa–2(a)(2)) requires manufacturers that disseminate information to submit to FDA semiannually a list that identifies the categories of providers who received the articles and reference publications. Section 99.501(b)(2) also requires the list to identify which category of recipients received each particular article or reference publication. If each of the 297 submissions under part 99 results in disseminated information, § 99.501(b)(2) would result in 594 lists (297 submissions x 2 submissions/year) identifying which category of recipients received each particular article or reference publication. The agency estimates the burden to be only 1 hour per response because this type of information is maintained as a usual and customary business practice, and the total burden for this provision is 594 hours (594 lists x 1 hour per list).

In relation to § 99.201(a)(2), § 99.501(b)(3) requires the manufacturer to provide, on a semiannual basis, a notice and summary of any additional clinical research or other data relating to the safety and effectiveness of the new use and, if it possesses such research or data, to provide a copy to FDA. This burden should not be as extensive as that in § 99.201(a)(2), so FDA estimates the burden to be 20 hours per response, for a total burden of 11,880 hours for this provision (297 annual responses submitted semiannually x 20 hours per response = 297 x 2 x 20 = 11,880 hours).

If a manufacturer discontinues or terminates a study before completing it, § 99.501(b)(4)) requires the manufacturer to state the reasons for discontinuing or terminating the study in its next progress report. Based on FDA's regulatory experience in monitoring studies to support supplemental applications, FDA estimates this would affect only 1 percent of all applications (297 x 0.01 = 2.97, rounded up to 3) and only 2 manufacturers (172 x 0.01 = 1.72, rounded up to 2). FDA estimates 2 hours of reporting time for this requirement because the manufacturer should know the reasons for discontinuing or terminating the study and would only need to provide those reasons in its progress report. The total burden hours for this provision is 6 hours (3 annual responses x 2 hours per response).

Section 99.501(b)(5) requires the manufacturer to submit any new or additional information that relates to whether the manufacturer continues to meet the requirements for the exemption after an exemption has been granted. FDA cannot determine, at this time, how many exemption requests will be granted, but, for purposes of this information of collection, has estimated that 10 percent of all submissions will contain an exemption request (297 total submissions x 0.10 = 29.7, rounded up to 30) and has assumed that all exemption requests will be granted, for a total of 30 annual responses. The information sought under § 99.501(b)(5) pertains solely to new or additional information and is not expected to be as extensive as the information required to obtain an exemption. Thus, FDA tentatively estimates the burden for § 99.501(b)(5) to be 41 hours per response (or half the burden associated with an exemption request), for a total burden of 1,230 hours for this provision (30 annual responses x 41 hours per response).

Section 99.501(c) requires the manufacturer to maintain records for 3 years after it has ceased dissemination of the information. FDA estimates the burden hour for this provision to be 1 hour. Because 297 annual responses are expected under § 99.501(c), the total burden for this provision is 297 hours.

Description of Respondents: All manufacturers (persons and businesses, including small businesses) of drugs, biologics, and device products.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
99.201(a)(1)	172	1.7	297	40	11,880
99.201(a)(2)	172	1.7	297	24	7,128
99.201(a)(3)	172	1.7	297	1	297
99.201(a)(4)(i)(A)	52	1.7	89	30	2,670
99.201(a)(4)(ii)(A)	52	1.7	89	60	5,340

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