application for ZELNORM (U.S. Patent No. 5,510,353) from Novartis Pharmaceuticals, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 18, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZELNORM 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 ZELNORM is 2,826 days. Of this time, 1,931 days occurred during the testing phase of the regulatory review period, while 895 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 30, 1994. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 30, 1994.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: February 11, 2000. FDA has verified the applicant's claim that the new drug application (NDA) for ZELNORM (NDA 21–200) was initially submitted on February 11, 2000.

3. *The date the application was approved*: July 24, 2002. FDA has verified the applicant's claim that NDA 21–200 was approved on July 24, 2002.

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 1,888 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by May 14, 2004. 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 13, 2004. 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 Division of Dockets Management. Three copies of any mailed 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 19, 2004.

Jane A. Axelrad,

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

[FR Doc. 04–5758 Filed 3–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0170]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Commitment Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is required, under the Food and Drug Administration Modernization Act of 1997 (Modernization Act), to report annually in the **Federal Register** on the status of postmarketing study commitments made by sponsors of approved drug and biological products. This is the agency's report on the status of the studies sponsors have agreed to or are required to conduct.

FOR FURTHER INFORMATION CONTACT:

Beth Duvall-Miller, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–20), 5600 Fishers Lane, Rockville, MD 20857, 301–594–3937; or

Robert Yetter, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM–25), 1400 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Section 130(a) of the Modernization Act (Public Law 105–115) amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision requiring reports of certain postmarketing studies (section 506B of the act (21 U.S.C. 356b)) for human drug and biological products. Section 506B of the act provides FDA with additional authority to monitor the progress of a postmarketing study commitment that an applicant has been required or has agreed to conduct by requiring the applicant to submit a report annually providing information on the status of the postmarketing study commitment. This report must also include reasons, if any, for failure to complete the commitment.

On December 1, 1999 (64 FR 67207), FDA published a proposed rule providing a framework for the content and format of the annual progress report. The proposed rule also clarified the scope of the reporting requirement and the timing for submission of the annual progress reports. The final rule, published on October 30, 2000 (65 FR 64607), modified annual report requirements for new drug applications (NDA) and abbreviated new drug applications (ANDA) by revising § 314.81(b)(2)(vii) (21 CFR 314.81(b)(2)(vii)). The rule also created a new annual reporting requirement for biologics license applications (BLA) by establishing § 601.70 (21 CFR 601.70). These regulations became effective on April 30, 2001. The regulations apply only to human drug and biological products. They do not apply to animal drug or to biological products that also meet the definition of a medical device.

Sections 314.81(b)(2)(vii) and 601.70 apply to postmarketing commitments made on or before enactment of the Modernization Act (November 21, 1997) as well as those made after that date. Sections 314.81(b)(2)(vii) and 601.70 require applicants of approved drug and biological products to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study that is required by FDA (e.g., accelerated approval clinical benefit studies) or that they have committed to conduct either at the time of approval or after approval of their NDA, ANDA, or BLA. The status of other types of postmarketing commitments (e.g., those concerning chemistry, manufacturing, production controls, and studies conducted on an applicant's own initiative) are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70, and are not addressed in this report. It should be noted, however, that applicants are required to report to FDA on these commitments made for NDAs and ANDAs under § 314.81(b)(2)(viii).

According to the regulations, once a postmarketing study commitment has been made, an applicant must report on the progress of the commitment on the anniversary of the product's approval until the postmarketing study commitment is completed or terminated, and FDA determines that the postmarketing study commitment has been fulfilled or that the postmarketing study commitment is either no longer feasible or would no longer provide useful information. The annual progress report must include a description of the postmarketing study commitment, a schedule for completing the study commitment, and a characterization of the current status of the study commitment. The report must also provide an explanation of the postmarketing study commitment's status by describing briefly the postmarketing study commitment's progress. A postmarketing study commitment schedule is expected to include the actual or projected dates for the following: (1) Submission of the study protocol to FDA, (2) completion of patient accrual or initiation of an animal study, (3) completion of the study, and (4) submission of the final study report to FDA. The postmarketing study commitment status must be described in the annual report according to the following definitions:

- Pending: The study has not been initiated, but does not meet the criterion for delayed;
- Ongoing: The study is proceeding according to or ahead of the original schedule;
- Delayed: The study is behind the original schedule;
- Terminated: The study was ended before completion, but a final study report has not been submitted to FDA; or
- Submitted: The study has been completed or terminated, and a final study report has been submitted to FDA.

Databases containing information on postmarketing study commitments are maintained at the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Information in this report covers any postmarketing study commitment that was made, in writing, at the time of approval or after approval of an application or a supplement to an application, including those required (e.g., to demonstrate clinical benefit of a product following accelerated approval) and those agreed to with the applicant. Information summarized in this report includes: (1) The number of applicants with open (uncompleted) postmarketing commitments; (2) the number of open postmarketing commitments; (3) the status of open postmarketing commitments as reported in § 314.81(b)(2)(vii) or § 601.70 annual reports; (4) the status of concluded postmarketing studies as determined by FDA; and (5) the number of open postmarketing commitments for which FDA did not receive an annual report.

Additional information about postmarketing study commitments made by sponsors to CDER and CBER are provided on FDA's Web site at *http://www.fda.gov/cder*. Like this notice, the site does not list postmarketing study commitments containing proprietary information. It is FDA policy not to post information on the Web site until it has been reviewed for accuracy. The information currently available on the Web site includes only postmarketing study commitments made since January 1, 1991. The numbers published in this notice cannot be compared with the numbers resulting from searches of the Web site. This notice incorporates totals for all postmarketing study commitments in the FDA databases, including those made prior to 1991 as well as those undergoing review for accuracy. The report in this notice will be updated annually while the Web site will be updated quarterly (in April, July, October, and January).

II. Summary of Information From Postmarketing Study Progress Reports

This report summarizes the status of postmarketing commitments as of September 30, 2003. If a commitment did not have a schedule or a postmarketing progress report was not received, the commitment is categorized according to the most recent information available to the agency.

Data in table 1 are numerical summaries generated from FDA databases. The data are broken out according to application type (NDAs/ANDAs or BLAs).

TABLE 1.—SUMMARY OF POSTMARKETING STUDY COMMITMENTS (NUMBERS AS OF SEPTEMBER 30, 2003)

	NDAs/ANDAs (% of Total)	BLAs (% of Total)
Applicants with open postmarketing commitments	122	48
Number of open postmarketing commitments	1,338	278
Status of open postmarketing commitments		
• Pending	864 (65%)	69 (25%)
• Ongoing	268 (20%)	108 (39%)
• Delayed	21 (2%)	32 (12%)
• Terminated	5 (0.4%)	5 (2%)
• Submitted	180 (13%)	64 (23%)
Concluded studies (October 1, 2002, through September 30, 2003)	79	69
• Commitment met	74 (94%)	62 (90%)
• Commitment not met	0 (0%)	1 (1%)
• Study no longer needed or feasible	5 (6%)	6 (9%)
Open postmarketing commitments with annual report due but not received	22 (6%)	35 (17%)

Dated: March 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5757 Filed 3–12–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Partner and Customer Satisfaction Surveys

SUMMARY: Under the provisions of section 3506(c)(2)(A) (of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Center for Scientific Review (CSR), National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 3, 2003, page 62304 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Customer Satisfaction Surveys. *Type of Information Collection Request:* Reinstatement. *Need and Use of Information Collection:* The information collected in these surveys will be used by the Center for Scientific Review management and personnel: (1) To assess the quality of the modified operations and processes now used by CSR to review grant applications; (2) to assess the quality of service provided by CSR to our customers; (3) to examine and assess the effectiveness of the reorganization and reconfiguration of the peer review study committees based on customer input; (4) to develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The survey for customers, *i.e.,* past and present grant applicants, is generic, but will have slight variations tailored to the scientific subject category of each major Integrated Review Group (IRG). The next major reorganized IRGs to be evaluated consist of the Behavioral and Social Sciences peer review study sections. Surveys will be collected via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center.

Frequency of Response: The participants will respond once, unless there is a compelling reason for a subsequent survey.

Affected Public: Universities, not-for-profit institutions, business or other for-profit, small businesses and organizations, and individuals. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: It is estimated that the survey form will take 20 minutes to complete. The estimated annual cost burden for respondents for each year for which the generic clearance is requested is $16,000 for FY 2004, $13,333 for FY 2005, $18,667 for FY 2006, and $24,000 for FY 2007. Thus, the combined total FY 2004–2007 potential hour burden on the respondents is estimated to be 1,800 hours for 5,400 respondents for all surveys which would be conducted under this generic clearance. If all planned surveys are conducted, the total four-year cost to respondents is estimated to be $72,000. Respondents should incur no additional costs. There will be dissemination and analysis costs for the survey originators. There are no capital, operating, or maintenance costs to report.

REQUESTS FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the CSR, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are to respond while maintaining their anonymity, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact: Karl F. Malik, Ph.D., Assistant to the Deputy Director, Office of the Director, Center for Scientific Review, National Institutes of Health, Rockledge II, Rm 3016, 6701 Rockledge Drive, Bethesda, MD 20814–9692, or call non-toll free: 301–435–1114, or e-mail your request or comments, including your address to: *malikk@csr.nih.gov*.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Brent Stanfield,

Acting Director, Center for Scientific Review, National Institutes of Health.

[FR Doc. 04–5814 Filed 3–12–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement for the Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research Facility in Galveston, TX

AGENCY: National Institutes of Health (NIH), HHS.

ACTION: Notice of intent to prepare an environmental impact statement for the Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research facility in Galveston, TX.

SUMMARY: The Department of Health and Human Services (DHHS), National Institutes of Health (NIH), announces its intent to prepare an environmental impact statement (EIS) to evaluate a proposed new National Laboratory for Biodefense and Emerging Infectious Diseases Research facility in Galveston, TX. This EIS is being prepared and considered in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969, regulations of the President's