

original PMAs, therefore, is 18,275 hours (1,075 approved PMAs with clinical data x 17 hours per PMA).

The applicant determines which records should be maintained during product development to document and/or substantiate the device's safety and effectiveness. Records required by the current good manufacturing practices for medical devices regulation (21 CFR part 820) may be relevant to a PMA review and may be submitted as part of an application. In individual instances, records may be required as conditions to approval to ensure the device's continuing safety and effectiveness.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-15662 Filed 7-8-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0275]

Agency Emergency Processing Under Office of Management and Budget Review; Application for Participation in the Medical Device Fellowship Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is for an application form

for participation in the medical device fellowship program (MDFP). FDA will use the information collected to identify qualified health professionals and students to provide expertise in the Center for Drugs and Radiological Health (CDRH) regulatory process for medical devices.

DATES: Fax written comments on the collection of information by August 9, 2004. FDA is requesting approval of this emergency processing by August 23, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-205-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. This information is needed immediately so that the agency can effectively recruit outside expertise to aid in the review of medical device marketing applications. Outside experts are needed to fill gaps in current expertise and provide a flexible workforce capable of addressing changing medical device technology. A formal application and collection process would enable FDA to collect the necessary information from applicants in a timely and consistent manner. The application form will provide clear

directions for applicants on what information to submit and a user-friendly format for submitting it, as well as reduce administrative costs for CDRH in collecting the information. The information to be collected is not available elsewhere.

With respect to the following collection of information FDA invites comments on these topics: (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.

Application for Participation in the Medical Device Fellowship Program; Form FDA 3608

Collecting applications for the MDFP will allow CDRH to easily and efficiently elicit and review information from students and health care professionals who are interested in becoming involved in CDRH activities. The process will reduce the time and cost of submitting written documentation to the agency and lessen the likelihood of applications being misrouted within the agency mail system. It will assist the agency in promoting and protecting the public health by encouraging outside persons to share their expertise with CDRH.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3608	100	1	100	1	100

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

FDA based these estimates on the number of inquiries we've received about the program and requests for application forms over the past year. We anticipate the number of interested individuals and universities, and subsequent number of applications, to increase as we continue to develop an outreach program and an alumni base.

In addition, we would expect applicants who are not selected for their preferred term of employment to reapply at a later date. For these reasons we would expect that the number of applications submitted in the second and third years would increase substantially. During the first year, we expect to receive 100 applications. We

believe that we will receive approximately 100 applications the second year and 100 applications the third year. FDA believes it will take individuals 1 hour to complete the application. This is based on similar applications submitted to FDA.

Dated: July 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Notice of Approval of Abbreviated New Animal Drug Application; Oxytocin Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's Center for Veterinary Medicine (CVM) is providing notice that it has approved an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group, Ltd. The ANADA provides for the veterinary prescription use of oxytocin injectable solution in ewes, sows, cows, and horses. The applicable section of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), CVM is providing notice that it has approved original ANADA 200-328 filed by Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland. ANADA 200-328 provides for the veterinary prescription use of Oxytocin Injection in ewes, sows, cows, and horses. Cross Vetpharm Group's Oxytocin Injection is approved as a generic copy of Phoenix Scientific, Inc.'s PVL Oxytocin Injectable, approved under NADA 124-241. The ANADA is approved as of May 21, 2004. The basis of approval is discussed in the freedom of information summary. The applicable sections of the regulation did not require amendment.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9

a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 14, 2004.

Linda Tollefson,

Acting Center Director, Center for Veterinary Medicine.

[FR Doc. 04-15570 Filed 7-8-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E-0249]

Determination of Regulatory Review Period for Purposes of Patent Extension; ELITEK

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ELITEK 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit written or electronic comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Claudia Grillo, Office of Regulatory Policy (HFD-013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-453-6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 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 biological 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 biological product ELITEK (rasburicase). ELITEK is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid-tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ELITEK (U.S. Patent No. 5,382,518) from Sanofi-Synthelabo, 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 biologic product had undergone a regulatory review period and that the approval of ELITEK 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 ELITEK is 2,360 days. Of this time, 1,420 days occurred during the testing phase of the regulatory review period, while 940 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,*