

sufficient information to support the removal of the clinical hold.

In the **Federal Register** of May 14, 1998 (63 FR 26809), FDA published a notice of availability of a guidance that described how applicants should submit responses to clinical holds so that they may be identified as complete responses and the agency can track the time to respond. FDA issued a revised guidance in October 2000.

The revised guidance states that FDA will respond in writing within 30 calendar days of receipt of a sponsor's request to release a clinical hold and a complete response to the issue(s) that led to the clinical hold. An applicant's complete response to an IND clinical hold is a response in which all clinical

hold issues identified in the clinical hold letter have been addressed.

The guidance requests that applicants type in large, bold letters at the top of the cover letter of the complete response "Clinical Hold Complete Response" to expedite review of the response. The guidance also requests that applicants submit the complete response letter in triplicate to the IND and that they fax a copy of the cover letter to the FDA contact person listed in the clinical hold letter who is responsible for the IND. The guidance requests more than an original and two copies of the cover letter in order to ensure that the submission is received and handled in a timely manner.

Based on data concerning the number of complete responses to clinical holds

received by the Center for Drug Evaluation and Research (CDER) in fiscal years 2001 and 2002, CDER estimates that approximately 41 responses are submitted annually from approximately 29 applicants, and that it takes approximately 284 hours to prepare and submit each response to CDER.

Based on data concerning the number of complete responses to clinical holds received by the Center for Biologics Evaluation and Research (CBER) in fiscal years 2001 and 2002, CBER estimates that approximately 123 responses are submitted annually from approximately 78 applicants, and that it takes approximately 284 hours to prepare and submit each response to CBER.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Complete Responses to Clinical Holds	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	29	approx. 1	41	284	11,644
CBER	78	1.58	123	284	34,932
Total					46,576

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

Dated: April 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03E-0032]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for IMAGENT 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 drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (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, 301-827-3460.

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 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 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 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 IMAGENT (perfluorohexane and DMPC). IMAGENT is indicated for use in subjects with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for IMAGENT (U.S. Patent No. 5,639,443) from Alliance Pharmaceutical Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 4, 2003, FDA advised the Patent and Trademark Office that this human drug product had