

**FOR FURTHER INFORMATION CONTACT:**

Larry Elliott, Executive Secretary,  
ABRWH, NIOSH, CDC, 4676 Columbia  
Parkway, Cincinnati, Ohio 45226,  
telephone 513/841-4498, fax 513/458-  
7125.

The Director, Management Analysis  
and Services Office, has been delegated  
the authority to sign **Federal Register**  
notices pertaining to announcements of  
meetings and other committee  
management activities for both CDC and  
the Agency for Toxic Substances and  
Disease Registry.

Dated: April 15, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services  
Office, Centers for Disease Control and  
Prevention.*

[FR Doc. 03-9689 Filed 4-18-03; 8:45 am]

**BILLING CODE 4163-19-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 02N-0282]

#### **Agency Information Collection Activities; Announcement of OMB Approval; Notice of Participation**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug  
Administration (FDA) is announcing  
that a collection of information entitled  
“Notice of Participation” has been  
approved by the Office of Management  
and Budget (OMB) under the Paperwork  
Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**  
JonnaLynn P. Capezzuto, Office of  
Information Resources Management  
(HFA-250), Food and Drug  
Administration, 5600 Fishers Lane,  
Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the  
**Federal Register** of December 30, 2002  
(67 FR 79639), the agency announced  
that the proposed information collection  
had been submitted to OMB for review  
and clearance under 44 U.S.C. 3507. An  
agency may not conduct or sponsor, and  
a person is not required to respond to,  
a collection of information unless it  
displays a currently valid OMB control  
number. OMB has now approved the  
information collection and has assigned  
OMB control number 0910-0191. The  
approval expires on April 30, 2006. A  
copy of the supporting statement for this  
information collection is available on  
the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: April 14, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-9662 Filed 4-18-03; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. 03N-0142]

#### **Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds**

**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, and to allow 60 days for  
public comment in response to the  
notice. This notice solicits comments on  
the collection of information contained  
in a guidance for industry entitled  
“Guidance for Industry on Submitting  
and Reviewing Complete Responses to  
Clinical Holds.” The guidance describes  
how to submit a complete response if an  
investigational new drug (IND)  
application is placed on clinical hold by  
FDA.

**DATES:** Submit written or electronic  
comments on the collection of  
information by June 20, 2003.

**ADDRESSES:** Submit electronic  
comments on the collection of  
information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. 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 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,  
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.

#### **Guidance for Industry on Submitting and Reviewing Complete Responses to Clinical Holds**

Section 117 of the Food and Drug  
Administration Modernization Act  
(Public Law 105-115), signed into law  
by President Clinton on November 21,  
1997, provides that a written request to  
FDA from the applicant of an  
investigation that a clinical hold be  
removed shall receive a decision in  
writing, specifying the reasons for that  
decision, within 30 days after receipt of  
such request. A clinical hold is an order  
issued by FDA to the applicant to delay  
a proposed clinical investigation or to  
suspend an ongoing investigation for a  
drug or biologic. An applicant may  
respond to a clinical hold.

Under section 505(i)(3)(C) of the  
Federal Food, Drug, and Cosmetic Act  
(21 U.S.C. 505(i)(3)(C)), any written  
request to FDA from the sponsor of an  
investigation that a clinical hold be  
removed must receive a decision, in  
writing and specifying the reasons,  
within 30 days after receipt of the  
request. The request must include

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 BURDEN<sup>1</sup>

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

<sup>1</sup> 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.*

[FR Doc. 03-9664 Filed 4-18-03; 8:45 am]

BILLING CODE 4160-01-S

## 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