

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]

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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.

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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