events in adults; Vaccine Adverse Effects Registry update; varicella vaccine; hepatitis A vaccine post-marketing surveillance; long-term stable funding for the Large-Linked Database; discussion of the draft NVAC paper on Vaccine Research Partnerships; serologic correlates of DTaP protection; update on NVAC funding of unmet needs; children's vaccine initiative; the immunization registry; the NVPO directorship; and the NVAC committee nominations.

Name: Subcommittee on Vaccine Safety and the Advisory Commission on Childhood Vaccines Subcommittee on Vaccine Safety.

Time and Date: 2:30 p.m.–5 p.m., May 6, 1996.

Place: Hubert H. Humphrey Building, Room 425A., 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: This joint ACCV/NVAC subcommittee will review issues relevant to vaccine safety and adverse reactions to vaccines.

Matters to be Discussed: The Subcommittee will discuss the report from the Task Force on Safer Childhood Vaccines interagency working group; expanding the Vaccine Injury Compensation Program to include adult immunizations and immunizations in special populations; visibility of a trust fund and administrative resources; and lessons from the swine flue experience.

Name: Subcommittee on Immunization Coverage.

Time and Date: 2:30 p.m.–5 p.m., May 6, 1996.

Place: Hubert H. Humphrey Building, Room 423A, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: The Subcommittee on Immunization Coverage will identify strategies and policy options by which to further improve the levels of immunization coverage.

Matters to be Discussed: The Subcommittee will discuss financing of an immunizations forum and prioritize findings from the forum, and previous committee work.

Name: Subcommittee on Future Vaccines.

Time and Date: 2:30 p.m.–5 p.m., May 6, 1996.

Place: Hubert H. Humphrey Building, Room 405A, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: The Subcommittee on Future Vaccines will develop policy options and guide national activities which will lead to accelerated development, licensure, and best use of new vaccines in the simplest possible immunization schedules.

Matters to be Discussed: The Subcommittee will identify the matrix of interactions and partnerships, via specific case studies; describe the process of priority-setting by each of the members of the vaccine research and development community, and define barriers to new vaccine development.

Agenda items for each meeting are subject to change as priorities dictate.

Contact Person for More Information: Gloria A. Kovach, Committee Management Specialist, National Vaccine Program Office, CDC, 1600 Clifton Road, NE, M/S D50, Atlanta, Georgia 30333, telephone 404/639–7250.

Dated: April 15, 1996.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–9688 Filed 4–18–96; 8:45 am]

BILLING CODE 4163–18–M

National Committee on Vital and Health Statistics Subcommittee on Mental Health Statistics Meeting: Date Change

Federal Register Citation of Previous Announcement 61 FR 13504—dated March 27, 1996.

Summary: Notice is given that the meeting and date for the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Mental Health Statistics, of the Centers for Disease Control and Prevention (CDC) has changed. The meeting time, place, status, purpose, and matters to be discussed announced in the original notice remain unchanged.

Original Date: May 2, 1996.

New Date: May 22, 1996.

Contact Person for More Information: Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: April 12, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–9660 Filed 4–18–96; 8:45 am]

BILLING CODE 4163–18–M

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Disability and Long-Term Care Statistics and NCVHS Subcommittee on Mental Health Statistics: Meeting

Pursuant to Pub. L. 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: NCVHS Subcommittee on Disability and Long-Term Care Statistics and NCVHS Subcommittee on Mental Health Statistics.

Time and Date: 9 a.m.–5 p.m., May 21, 1996.

Place: Room 503A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open.

Purpose: The Subcommittee on Disability and Long-Term Care Statistics and the Subcommittee on Mental Health Statistics will meet jointly to conduct a fact finding meeting to discuss disability and long-term care data needs with representatives from States, educational and trade organizations.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: April 12, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–9687 Filed 4–18–96; 8:45 am]

BILLING CODE 4163–18–M

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on State and Community Health Statistics: Meeting

Pursuant to Pub. L. 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following subcommittee meeting.

Name: NCVHS Subcommittee on State and Community Health Statistics.

Time and Date: 9 a.m.–5 p.m., May 8, 1996.

Place: Room 503A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open.

Purpose: The Subcommittee will conduct a fact finding meeting with State and private sector health professionals to learn the status of information available to influence public health and health care decisions. In particular, data availability and needs for community health assessment will be discussed.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/435–7050.

Dated: April 12, 1996.

Carolyn J. Russel,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–9689 Filed 4–18–96; 8:45 am]

BILLING CODE 4163–18–M

Food and Drug Administration

[Docket No. 96N–0069]

Agency Information Collection Activities: Proposed Collection; Comment Request; Extension

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, Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the approval of investigational new drug applications and subsequent reporting and recordkeeping requirements.

DATES: Submit written comments on the collection of information by June 18, 1996.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c). To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

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.

Investigational New Drug (IND) Regulations (21 CFR 312) (OMB Control Number 0910–0014—Extension)

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355 (i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs can be conducted. The IND information requirements are needed to ensure the safe and ethical investigation of the safety and effectiveness of new drugs.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective and be properly manufactured and properly labeled for their intended uses. The act provides in 21 U.S.C. 355(a) that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts.

The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study.

The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements is dictated by the scientific procedures and human subject safeguards which must be followed in the clinical tests of IND's. FDA estimates the burden of the information collection provisions of the IND regulations as follows:

Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
312.7	7	1	7	24 hours	168
312.10	?	?	?	?	?
312.23	1,623	1	1,623	100 hours	162,300
312.30	1,201	9	10,809	84 hours	907,956
312.31	880	5.64	4,963	8 hours	39,704
312.32	440	8	3,520	20 hours	70,400
312.33	1,517	2.6	3,944	450 hours	1,774,800
312.35	5	1	5	260 hours	1,300
312.36	300	1	300	5 hours	1,500
312.38	579	1.2	695	45 minutes	521
312.44	?	?	?	?	?
312.45	205	1.4	287	5 hours	1,435
312.47	?	?	?	?	?
312.55	?	?	?	?	?
312.56	560	2.4	1,344	84 hours	112,896
312.58	260	2.6	676	84 hours	56,784
312.64	?	?	?	?	?
312.66	?	?	?	?	?
312.83	5	1	5	160 hours	800
312.85	260	2.6	676	960 hours	648,960
312.110	30	11.6	348	24 hours	8,352
312.120(b)	560	2.4	1,344	100 hours	134,000
312.120(c)(3)	560	2.4	1,344	3 hours	4,032

There are no capital costs or operating and maintenance costs associated with this collection. Where question marks appear in the burden estimate, FDA does not have current information available. Public comments will be greatly appreciated.

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
312.52	280	1	280	30 minutes	140
312.53	4,000	1	4,000	84 hours	336,000
312.57	560	2.4	1,344	100 hours	134,400
312.59	250	2.4	600	8 hours	4,800
312.62(a)	4,000	1	4,000	40 hours	160,000
312.62(b)	4,000	10	40,000	40 hours	1,600,000
312.160(a)	250	40	10,000	30 minutes	5,000
312.160(c)	250	30	7,500	30 minutes	3,750
Total Burden Hours					6,170,398

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

Dated: April 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9674 Filed 4–18–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0118]

Drug Export; ORTHO™ HIV–1/HIV–2 Ab–Capture ELISA Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ortho Diagnostic Systems, Inc., has filed an application requesting approval for the export of the human biological product ORTHO™ HIV–1/HIV–2 Ab–Capture ELISA Test System to Australia, Austria, Belgium, Canada, Denmark, The Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and The United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–2006.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of human biological products that are not currently approved in the