

Board of Governors of the Federal Reserve System, October 3, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97-26735 Filed 10-8-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Meetings

Notice of two meetings of the National Bioethics Advisory Commission (NBAC), one each of its genetics and human subjects subcommittees, and a brief joint session of the full Commission.

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of two meetings of the National Bioethics Advisory Commission and a brief joint session of the full Commission. Commission members will discuss the protection of the rights and welfare of human subjects in research including decisionally and/or cognitively impaired populations and will address the use of genetic information involved in tissue storage. The meetings are open to the public and opportunities for statements by the public will be provided.

Dates/times	Locations
Human Subjects Subcommittee, October 19, 1997, 7:30 am–4:30 pm.	National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10, Bethesda, Maryland 20892.
11:30 am–1:30 pm	Full Commission Meeting, Conference Room 10.
Genetics Subcommittee, October 19, 1997, 7:30 am–4:30 pm.	National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 9, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995 for an initial two years. An amendment to Executive Order 12975, dated May 16, 1997, extended the term of the Commission for an additional two years. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council and other entities on bioethical issues arising from the research on human biology and behavior, and in the

applications of that research including clinical applications.

Public Participation

All meetings are open to the public with attendance limited by the availability of space. Members of the public who wish to present oral statements should contact Ms. Patricia Norris by telephone, fax machine, or mail as shown below prior to the meeting as soon as possible. Individuals unable to make oral presentations are encouraged to mail or fax their comments to the NBAC staff office for distribution to the subcommittee or Commission members and inclusion in the public record. Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Norris, National Bioethics Advisory Commission, MSC-7508, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892-7508, telephone 301-402-4242, fax number 301-480-6900.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director, Acting, National Bioethics Advisory Commission.

[FR Doc. 97-26866 Filed 10-8-97; 8:45 am]

BILLING CODE 4160-17-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Minimizing Medical Product Errors—A Systems Approach; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Minimizing Medical Product Errors—A Systems Approach." The purpose of this workshop is to provide a forum for an open exchange with industry, health professionals, consumers, and others on issues relating to minimizing the potential for medical product errors due to similarities in drug names, similar labeling, design and packaging of human drugs, biologics, blood/blood products, vaccines, and medical devices.

DATES: The public workshop will be held on Thursday, January 8, 1998, 7:30 a.m. to 6 p.m. An open public hearing to present comments, 4:15 p.m. to 5:45 p.m. Submit written abstracts by

November 7, 1997. Submit written notices of participation by December 5, 1997. There is no registration fee for this workshop, however, because seating is limited interested persons are encouraged to register by December 15, 1997.

ADDRESSES: The public workshop will be held at Natcher Auditorium, National Institutes of Health, 45 Center Dr., Bethesda, MD. Submit written abstracts and notices of participation to Mary C. Gross (address below).

FOR FURTHER INFORMATION CONTACT:

For general information: Mary C.

Gross, Office of External Affairs (HF-60), Food and Drug Administration, 5600 Fishers Lane, rm. 14C-03, Rockville, MD 20857, 301-827-3440, FAX 301-594-0113, e-mail

MGROSS@BANGATE.FDA.GOV.

For information regarding the scientific paper selection process:

Jerry Phillips, Center for Drug Evaluation and Research, 7500 Standish Pl., rm. N271, Rockville, MD 20852, 301-827-5840, FAX 301-594-0183, e-mail PHILLIPSJ@A1@FDA.CD.

SUPPLEMENTARY INFORMATION:

I. Background

FDA will explore the extent of user error occurring with FDA-regulated products; collect data to help FDA determine what methods, if any, already exist to assess the potential for medical product errors; hear discussion from outside groups about the appropriate role for FDA in minimizing medical product errors; and discuss how the agency can effectively collaborate in minimizing user errors.

II. Submission of the Abstracts

For purposes of discussion at the workshop, FDA is requesting abstracts that discuss how best to minimize the incidence of user error with FDA-regulated products. FDA will select a limited number of abstracts that contain information on what methods, if any, already exist to assess the potential for user error in relation to labeling, packaging, and design of FDA-regulated products for formal presentation at the workshop.

The abstracts should be printed (typewritten or computer) within the confines of an 8 1/2 x 11-inch page of white paper. All lines should be single spaced with a three-letter indent for each paragraph. The title should be brief and capitalized. The authors name(s) should then be listed, underlining each, then list agency, institution, or facility involved.

The body of the abstract must be organized in the following manner:

- (1) A brief statement of purpose,
- (2) A statement of methods used,
- (3) A statement of results obtained, and
- (4) A statement of conclusions reached.

Each presenter should submit a current curriculum vitae with the abstract.

Interested persons who wish to speak should submit a written notice of participation including a name, affiliation, address, phone number, and summary of remarks. FDA will allocate the time available for the hearing among the persons who properly file notices of their intent to make a presentation at the meeting. If time permits, FDA may allow additional presentations from interested persons attending the meeting who did not submit a written notice of participation to make a presentation.

Dated: October 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-26707 Filed 10-8-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Excise Tax Revision and Coverage of New Vaccines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: On August 5, 1997, the President signed Pub. L. 105-32, the "Taxpayer Relief Act of 1997," containing amendments to revise the excise tax structure to a flat rate of 75 cents per dose for each vaccine covered under the National Vaccine Injury Compensation Program (VICP). The amendments also make effective the coverage of three new vaccines under the VICP.

The VICP, established by Subtitle 2 of Title XXI of the Public Health Service Act (the Act), provides a system of no-fault compensation for certain individuals who have been injured by specific childhood vaccines. The Vaccine Injury Table (the Table), included in the Act, establishes presumptions about causation of certain illnesses and conditions which are used by the U.S. Court of Federal Claims to adjudicate petitions. The Act provides that a revision to the Table, based on the

addition of new vaccines under section 2114(e) of the Act, shall take effect upon the effective date of a tax enacted to provide funds for compensation for injuries from vaccines that are added to the Table. See section 13632(a)(3) of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66 enacted August 10, 1993.

EFFECTIVE DATE: August 6, 1997.

FOR FURTHER INFORMATION CONTACT:

Thomas E. Balbier, Jr., Director, Division of Vaccine Injury Compensation, Bureau of Health Professions, (301) 443-6593.

SUPPLEMENTARY INFORMATION: Section 904(a) of the Taxpayer Relief Act of 1997 provides that the excise tax on all covered vaccines is 75 cents per dose and that combinations of vaccines are subject to an excise tax which is the sum of the amounts for each vaccine included in the combination.

On February 20, 1997, a Final rule was published in the **Federal Register** (62 FR 7685) announcing the addition of hepatitis B, Hib, and varicella vaccines to the Table. The Final rule states in § 100.3(c)(2) that the inclusion of hepatitis B, Hib, and varicella vaccines and other new vaccines (Items VIII, IX, X, XI and XII of the Table) will be effective on the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines.

Section 904(b) of the Taxpayer Relief Act of 1997 provides for an excise tax for these three new vaccines, effective August 6, 1997, and this notice serves as an announcement of such a tax. Accordingly, petitions for compensation for injuries or deaths related to hepatitis B, Hib, and varicella vaccines may now be filed under the VICP. In accordance with section 2116(b) of the Act, for injuries or deaths that occurred before August 6, 1997, for these three vaccines, petitions may be filed no later than August 6, 1999, provided that the injury or death occurred no earlier than August 6, 1989.

A document will be published in the **Federal Register** to amend the CFR to include a date certain (August 6, 1997) in § 100.3(c), so that there will be no uncertainty as to the coverage of these three vaccines.

Dated: October 2, 1997.

Claude Earl Fox,

Acting Administrator.

[FR Doc. 97-26706 Filed 10-8-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Alternate Method of Acquisition for Health Care Services; Authorized by the Federal Acquisition Regulations

AGENCY: Indian Health Service, HHS.

ACTION: General notice.

SUMMARY: The Indian Health Service (IHS) issues this General Notice to inform the public that IHS has adopted the Rate Quotation as an alternate acquisition method to establish reimbursement rates for health care services purchased by its Contract Health Services Program.

EFFECTIVE DATE: October 1, 1997.

FOR FURTHER INFORMATION CONTACT:

Ronald Freeman, Acting Director, Division of Managed Care, Room 6A-55, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3024 or Carol Silverman, Acting Director, Division of Acquisition and Grants Management, Suite 450A, 12300 Twinbrook Parkway, Rockville, MD 20857, (301) 443-5774. (These are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The IHS Contract Health Services program is administered under regulations at 42 CFR 36.21 et seq. and services purchased are governed by the Federal Acquisition Regulations (FAR). Under this program IHS purchases health care services from hospitals, physicians, and other health care facilities and providers to supplement the IHS direct care delivery system. The IHS last issued a payment policy in 51 FR 23540 on June 30, 1986. This policy requires the IHS Area Offices to enter into formal agreements with providers that they expect to use for health care services. With certain specified exceptions in the IHS Payment Policy, the formal agreement must provide for reimbursement of services at rates which do not exceed prevailing Medicare reimbursement rates (including deductibles and co-insurance), and the IHS service units will make patient referrals and procure all its routine health care services from providers with formal agreements.

The IHS issued a general notice in 56 FR 10566 on March 13, 1991 to inform the public that the IHS was conducting a pilot project in the IHS Portland Area. The project was designed to determine whether an alternative method of acquisition for contract health services would result in greater participation by health care providers and lower costs to IHS. The project was originally scheduled to end on March 31, 1992,