draft ''Immunotoxicity Testing Framework'' to deal specifically with testing for adverse effects of medical devices or constituent materials on the immune system. The draft guidance will provide medical device manufacturers with FDA's current thinking on immunotoxicity testing, and it will help to ensure a consistent and scientifically sound approach to the overall evaluation of product safety.

The draft guidance also contains a flow chart to determine if immunotoxicity testing is recommended, and three tables that lead sequentially from potential immunological effects, to potential responses commonly associated with those effects, to examples of testing that might be considered as part of the overall safety evaluation of finished devices or constituent materials.

In the past, guidances generally have been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. This guidance represents FDA's current thinking on the issue of immunotoxicity testing for medical devices and constituent materials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Request for Comments

Interested persons may, on or before June 16, 1997, submit to the Dockets Management Branch (address above) written comments regarding the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Received comments will be considered in determining whether to amend the current draft guidance document.

Dated: March 6, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–6715 Filed 3–17–97; 8:45 am]

BILLING CODE 4160–01–F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Oversight Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its clinical hold oversight committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held on May 13, 1997. Biological product companies may submit review requests for the May meeting by April 4, 1997.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, 5600 Fishers Lane, rm. 14–105, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may order a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug or biologic trials. Section 312.42 describes the grounds for ordering a clinical hold.

A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be ordered on one or more of the investigations covered by an investigational new drug application (IND). When a proposed study is placed on clinical hold, subjects may not be given the investigational drug or biologic as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug or biologic, and patients already in the study should stop receiving therapy involving the investigational drug or biologic unless FDA specifically permits it.

When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for ordering a clinical hold, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, a clinical hold may be ordered by or on behalf of the director of the division that is responsible for the review of the IND.

FDA regulations in § 312.48 provide dispute resolution mechanisms through which sponsors may request reconsideration of clinical hold orders. The regulations encourage the sponsor to attempt to resolve disputes directly with the review staff responsible for the review of the IND. If necessary, the sponsor may request a meeting with the review staff and management to discuss the clinical hold.

CBER began a process to evaluate the consistency and fairness of practices in ordering clinical holds by instituting a review committee to review clinical holds (see 61 FR 1033, January 11, 1996). CBER held its first clinical hold oversight committee meeting on May 17, 1995, and plans to conduct further quality assurance oversight of the IND process. The committee last met in February 1997. The review procedure of the committee is designed to afford an opportunity for a sponsor who does not wish to seek formal reconsideration of a pending clinical hold to have that clinical hold considered ''anonymously.'' The committee consists of senior managers of CBER, a senior official from the Center for Drug Evaluation and Research, and the FDA Chief Mediator and Ombudsman.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review some of the clinical holds proposed for review by biological product sponsors. In general, a biological product sponsor should consider requesting review when it disagrees with FDA's scientific or procedural basis for the decision.

Requests for committee review of a clinical hold should be submitted to the FDA Chief Mediator and Ombudsman, who is responsible for selecting clinical holds for review. The committee and CBER staff, with the exception of the FDA Chief Mediator and Ombudsman,

are never advised, either in the review process or thereafter, which of the clinical holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with FDA regulations and CBER policy.

The meetings of the oversight committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding confidential commercial information, may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites biological product companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational biological product trial that was placed on clinical hold during the past 12 months that they want the committee to review at its May 13, 1997, meeting. Submissions should be made by April 4, 1997, to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman (address above).

Dated: March 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6779 Filed 3–17–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration, HHS

Submitted for Collection of Public Comment: Submission for OMB Review (HCFA–R–4)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements contained in 42 CFR 447.253; *Form No.:* HCFA–R–4; *Use:* The Medicaid Management Information System (MMIS) is a State-operated, Federally mandated computer system used for automated Medicaid claims processing and information retrieval for program management. Data elements represent the Federally imposed recordkeeping requirements of MMIS; *Frequency:* Annually; *Affected Public:* Business or other for profit; State, local, or tribal government; *Number of Respondents:* 50; Total Annual Responses: 50; *Total Annual Hours:* 2,298,250.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: March 5, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–6789 Filed 3–17–97; 8:45 am]

BILLING CODE 4120–03–P

[Document Identifier: HCFA-R–201]

Correction Notice: Agency Information Collection Activities: Submission for Emergency OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Managed Care Organization, Incentive Arrangement Disclosure Form and Supporting Regulations 42 CFR 417.479, 417.500, 434.44, 434.67, 434.70, 1003.100, 1003.101, 1003.103, 1003.106; *Form No.:* HCFA–R–201; *Use:* Final rule OMC–10, published in the Federal Register on 12/31/96, disclosed to the public that the information collection requirements referenced in OMC–10-F, would be submitted to OMB for emergency review upon publication of the rule. However, Section V of final rule OMC–10 neglected to denote that the forms used to capture the information collection requirements referenced in OMC–10 would also be submitted to OMB as part of the emergency review. These forms which will be used to demonstrate and monitor compliance with statute governing physician incentives under Medicare and Medicaid managed care organizations, were created in an extensive cooperative effort with the American Association of Health Plans, State Medicaid Agency representatives, and the Medicaid Managed Care Technical Advisory group. Therefore, we are correcting this oversight and are requesting comment on the forms and supporting regulations. These forms are available for inspection on the HCFA website, on the Internet, at http://www.hcfa.gov; *Frequency:* Annually; *Affected Public:* Business or other for profit, not for profit institutions, state, local or tribal government, and federal government; *Number of Respondents:* 450; *Total Annual Responses:* 450; *Total Annual Hours:* 45,000.

To obtain copies of the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collection should be sent within 5 days of this notice directly to