ATSDR MINIMAL RISK LEVELS (MRLS) FOR HAZARDOUS SUBSTANCES—Continued

[March 1996]

Substance name	CAS No.	Route	Duration	Value	Factors	End point
1,3-DI-CHLORO-PROPENE.	000542–75–6	INHALATION	INTERMEDIATE	0.003 ppm	100	Respiratory.
		INHALATION	CHRONIC	0.002 ppm	100	Respiratory.
1,3-DI-NITRO-BENZENE	000099–65–0	ORAL	ACUTE	0.008 mg/kg/day	100	Reproductive.
		ORAL	INTERMEDIATE	0.0005 mg/kg/day	1000	Hematological.
1,4-DI-CHLORO-BENZENE.	000106–46–7	INHALATION	INTERMEDIATE	0.2 ppm	100	Hepatic.
		ORAL	INTERMEDIATE	0.1 mg/kg/day	100	Hepatic.
1-METHYLNAPHTHALENE.	000090–12–0	ORAL	CHRONIC	0.07 mg/kg/day	1000	Respiratory.
2,3,4,7,8-PENTACHLORO-DI-BENZOFURAN.	057117–31–4	ORAL	ACUTE	0.000001 mg/kg/day	3000	Immunological.
		ORAL	INTERMEDIATE	0.00000003 mg/kg/day.	3000	Hepatic.
2,3,7,8-TETRACHLORO-DIBENZO-P-DIOXIN.	001746–01–6	ORAL	ACUTE	0.0000001 mg/kg/day	1000	Hepatic.
		ORAL	INTERMEDIATE	0.000000001 mg/kg/day.	1000	Reproductive.
		ORAL	CHRONIC	0.000000001 mg/kg/day.	1000	Reproductive.
2,4,6-TRI-CHLORO-PHENOL.	000088–06–2	ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Reproductive.
2,4,6-TRI-NITROTOLUENE.	000118–96–7	ORAL	INTERMEDIATE	0.0005 mg/kg/day	1000	Hepatic.
2,4-DI-NITRO-PHENOL	000051–28–5	ORAL	ACUTE	0.01 mg/kg/day	100	Body Weight.
2,4-DI-NITRO-TOLUENE	000121–14–2	ORAL	ACUTE	0.06 mg/kg/day	1000	Hematological.
		ORAL	INTERMEDIATE	0.05 mg/kg/day	100	Reproductive.
		ORAL	CHRONIC	0.002 mg/kg/day	100	Hematological.
2,6-DI-NITRO-TOLUENE	000606–20–2	ORAL	INTERMEDIATE	0.04 mg/kg/day	100	Neurological.
4,4°-METHYL-ENE-BIS (2-CHLOROANILINE).	000101–14–4	ORAL	CHRONIC	0.003 mg/kg/day	3000	Hepatic.
4,6-DI-NITRO-O-CRESOL.	000534–52–1	ORAL	ACUTE	0.004 mg/kg/day	100	Neurological.
		ORAL	INTERMEDIATE	0.004 mg/kg/day	100	Neurological.

[FR Doc. 96–12991 Filed 5–22–96; 8:45 am]

BILLING CODE 4163–70–P

Food and Drug Administration

Advisory Committee; Science Board to the Food and Drug Administration; Formation of a Subcommittee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee of the Science Board to the Food and Drug Administration (Science Board). This subcommittee has been established to address issues related to science and research in FDA. The subcommittee's preliminary recommendations will be presented to the FDA Science Board for full public discussion at a future Science Board meeting.

FOR FURTHER INFORMATION CONTACT: Susan A. Homire, Office of Science (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is announcing the formation of a subcommittee to the Science Board to the Food and Drug Administration. This subcommittee has been established to address issues related to science and research in FDA. The subcommittee will meet several times over the next 6 to 9 months to develop preliminary recommendations for the Science Board on a process for review of research programs within FDA. During this period there will be opportunities for public comment; these opportunities will be announced in the Federal Register at least 15 days prior to each scheduled public meeting. The subcommittee's preliminary recommendations will be presented to the Science Board for full public discussion at a future Science Board meeting. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463 (5 U.S.C. app. 2)).

Dated: May 16, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–12877 Filed 5–22–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review 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 the clinical hold review 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 in August 1996. Biological product companies may submit review requests for the August meeting by June 28, 1996.

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–4), 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. FDA regulations in § 312.42 describe 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 (61 FR 1033, January 11, 1996). CBER held its first clinical hold review committee meeting on May 17, 1995. It will meet quarterly or semiannually. The committee last met in May 1996. 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 review 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 August 1996 meeting. Submissions should be made by June 1, 1996, to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: May 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–13042 Filed 5–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA 301]

Agency Information Collection Activities: Proposed Collection; Comment Request

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:* Revision of a currently approved collection; *Title of Information Collection:* Certification of Medicaid Eligibility Quality Control (MEQC) Payment Error Rates; *Form No.:* HCFA–301; *Use:* This certification is the new form by which States will report their MEQC payment error rate findings. This form represents aggregate data which were formerly collected through the Integrated Review Schedule; *Frequency:* Semi-annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:*