be, and it hereby is, set aside, as to respondent Rubber Manufacturers, as of the effective date of this order.

By the Commission.

Benjamin I. Berman,

Acting Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in Rubber Manufacturers Association, Inc., D. 5448 and D. 7505

I concur in the decision to grant the request of the Rubber Manufacturers Association, Inc. to set aside the 1948 order in Docket No. D. 5448 and the 1962 order in Docket No. D. 7505. I dissent from the decision to limit the setting aside of the order to the association, instead of setting aside the order in its entirety.

The decision to limit relief to the Rubber Manufacturers Association, one of forty-three respondents under the order appears to be inconsistent with the Commission's announced policy to presume ''that the public interest requires reopening and setting aside the order *in its entirety*'' (emphasis added) ''when a petition to reopen and modify a competition order is filed'' and the order is more than twenty years old.[1] The Commission's recognition of the limitations of the findings underlying an order[2] further suggests that the presumption that an order will be terminated after twenty years should apply to the order in its entirety and not be limited to the petitioner.[3]

I previously have expressed my concern that the adoption of a presumption instead of an across-the-board rule in favor of sunset ''will impose costs by requiring respondents to file individual petitions and the Commission to assess in the context of each such petition whether the presumption has been overcome for that order.''[4] Now the Commission would further increase the burden on both public and private resources by applying the presumption in favor of sunset not only on a case-by-case basis but on a respondent-by respondent basis.

The petition filed by the Rubber Manufacturers Association invoked the twenty-year presumption that the order should be set aside. No evidence of recidivist conduct by any of the forty-three respondents, having been presented to overcome the presumption,[5] the order should be set aside in its entirety.

[FR Doc. 95–20903 Filed 8–22–95; 8:45 am]

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[1] FTC, Statement of Policy with Respect to Duration of Competition Orders and Statement of Intention To Solicit Public Comment with Respect to Duration of Consumer Protection Orders (July 22, 1994), at 8 (hereafter ''Sunset Policy Statement'').

[2] ''[F]indings upon which [orders] are based should not be presumed to continue'' for longer than twenty years. Sunset Policy Statement at 4.

[3] The presumption of termination after 20 years applies authomatically for new orders in competition cases and is not limited to individual respondents, further supporting the view that the twenty-year presumption in favor of sunset for existing orders should apply to the order, not to particular respondents.

[4] Separate Statement of Commission Mary L. Azcuenaga on Sunset Policy (July 22, 1994), at 7 (footnote omitted).

[5] See Sunset Policy Statement at 8 n.19.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Investigational New Drugs; 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 holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in June 1995. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug 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 October 1995. Drug companies may submit review requests for the October meeting before September 22, 1995.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1306.

FOR FURTHER INFORMATION CONTACT: Deborah A. Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

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 impose 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 trials. 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 placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug 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, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

FDA regulations in § 312.42 describe the grounds for the imposition of a clinical hold. When FDA concludes that there is a deficiency in a proposed or ongoing clinical trial that may be grounds for the imposition of a hold order, ordinarily FDA will attempt to resolve the matter through informal discussions with the sponsor. If that attempt is unsuccessful, the agency may order a clinical hold. In CDER, a clinical hold is ordered by or on behalf of the

director of the division that is responsible for review of the IND. The order identifies the studies under the IND to which the hold applies and explains the basis for the action. The hold order may be made by telephone or other means of rapid communication, or in writing. Within 30 days of the imposition of the clinical hold, the division director provides the sponsor with a written explanation of the basis for the hold. Any sponsor who has not received a written explanation within 30 days should notify the division and request that it be issued. In addition to providing a statement of reasons, this ensures that the hold is recorded in CDER's management information system.

The clinical hold order specifies whether the sponsor may resume the affected investigation without prior notification by FDA once the deficiency has been corrected. If the order does not permit the resumption, an investigation may resume only after the division director or his or her designee has notified the sponsor that the investigation may proceed. Resumption may be authorized by telephone or other means of rapid communication. If all investigations covered by an IND remain on clinical hold for 1 year or longer, FDA may place the IND on inactive status.

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, a sponsor may request a meeting with the review staff and management to discuss the hold.

Over the years, drug sponsors have expressed a number of concerns about the clinical hold process, including concerns about the scientific and procedural adequacy of some agency actions. FDA undertook several initiatives to evaluate the consistency and fairness of the Center's practices in imposing clinical holds. First, CDER completed a centerwide review of clinical holds recorded in the management information system. While some differences in practice and procedure were discerned among divisions, it appeared that the procedures specified in the regulations were, in general, being followed, and that holds were scientifically supportable.

Second, FDA established a committee in CDER to review selected clinical holds for scientific and procedural quality. The committee held pilot meetings in 1991 and 1992. The trial phase of the committee review process confirmed the agency's view that the divisions in CDER impose clinical holds in a manner that is generally consistent with FDA's procedural requirements and that holds are imposed on scientifically supportable grounds.

The clinical hold committee review process is now a regular, ongoing program. 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 hold to have that hold considered ''anonymously.'' The committee consists of senior managers in CDER, a senior official from the Center for Biologics Evaluation and Research, and the FDA Chief Mediator and Ombudsman. The committee now meets semiannually. The committee last met in June 1995.

Clinical holds to be reviewed will be chosen randomly. In addition, the committee will review holds proposed for review by drug sponsors. In general, a drug sponsor should consider requesting review when it disagrees with the agency'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 CDER staff, with the exception of the FDA Chief Mediator and Ombudsman, are never advised, either in the review process or thereafter, which of the holds were randomly chosen and which were submitted by sponsors. The committee will evaluate the selected clinical holds for scientific content and consistency with agency regulations and CDER 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, will be available from the FDA Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and IND number of any investigational new drug trial that was placed on clinical hold during the past 12 months that they want the committee to review at its October meeting. Submissions should be made by September 22, 1995 to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman (address above).

Dated: August 15, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–20812 Filed 8–22–95; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory bodies scheduled to meet during the month of September 1995.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: September 13, 9:00 am–5:00 pm.

Place: Parklawn Building, Conference Room D, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

Agenda

Agenda items will include, but not be limited to: a report on the National Vaccine Program; a report on the Task Force for Safer Childhood Vaccines and Acellular Pertussis Vaccine Trials from the National Institutes of Health; Review of the American Academy of Pediatrics/Advisory Committee on Immunization Practices Polio and Pertussis Vaccine Recommendations; and routine Program reports.

Public comment will be permitted before noon and at the end of the Commission meeting, as time permits. Oral presentations will be limited to 5 minutes per public speaker.

Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to Mr. Jerry Anderson, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–35, 5600 Fishers Lane, Rockville, MD 20852; Telephone (301) 443–1533.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation,