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. 95–20902 Filed 8–22–95; 8:45 am]

BILLING CODE 6750–01–M

[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 automatically 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 Commissioner Mary L. Azcuenaga on Sunset Policy (July 22, 1994), at 7 (footnote omitted).

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

[Dkt. 7505]

Rubber Manufacturers Association, Inc., et al.; Prohibited Trade Practices and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Set aside order.

SUMMARY: This order reopens a 1962 consent order—which prohibited the Association from formulating or enforcing resale price agreements, exchanging resale price information or entering into price-fixing agreements—and sets aside the consent order as to respondent Rubber Manufacturers Association pursuant to the Commission's Sunset Policy Statement, under which the Commission presumes that the public interest requires terminating competition orders that are more than 20 years old.

DATES: Consent order issued January 6, 1962. Set aside order issued July 19, 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Piotrowski, FTC/S–2115, Washington, D.C. 20580. (202) 326–2623

SUPPLEMENTARY INFORMATION: In the Matter of Rubber Manufacturers Association, Inc., et al. The prohibited trade practices and/or corrective actions are removed as indicated.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Commissioners: Robert Pitofsky, Chairman, Mary L. Azcuenaga, Janet D. Steiger, Roscoe B. Starek, III, Christine A. Varney

In the Matter of—

Rubber Manufacturers Association, Inc., a trade association;
The Tire and Rim Association, Inc., a trade association;
The Goodyear Tire and Rubber Company, a corporation;
The Firestone Tire and Rubber Company, a corporation;
United States Rubber Company, a corporation;
The B.F. Goodrich Company, a corporation;
The General Tire and Rubber Company, a corporation;
The Armstrong Rubber Company, a corporation;
Cooper Tire and Rubber Company, a corporation;
The Dayton Rubber Company, a corporation;
Dunlop Tire and Rubber Corporation, a corporation;
The Gates Rubber Company, a corporation;
Lee Rubber and Tire Corporation, a corporation;
The Mansfield Tire and Rubber Company, a corporation;
McCreary Tire and Rubber Company, a corporation;
The Mohawk Rubber Corporation, a corporation; and
Seiberling Rubber Company, a corporation.

Order Reopening Proceeding and Setting Aside Order as to Respondent Rubber Manufacturers Association, Inc.

On March 17, 1995, Rubber Manufacturers Association, Inc. (''Rubber Manufacturers''), one of seventeen respondents named in this consent order,[1] filed its Petition to Reopen and Set Aside Consent Orders (''Petition'') in this matter. Rubber Manufacturers requests that the Commission set aside the 1962 consent order in this matter pursuant to section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), Rule 2.51 of the Commission's Rules of Practice, 16 C.F.R. 2.51, and the 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, issued on July 22, 1994, and published at 59 FR 45,286–92 (Sept. 11, 994) (''Sunset Policy Statement''). In the Petition, Rubber Manufacturers affirmatively states that it has not engaged in any conduct violating the terms of the order. The Petition was placed on the public record, and the thirty-day comment period expired on May 10, 1995. One comment, relating to general policy issues concerning the Commission's Sunset Policy Statement, was received.

The Commission in its July 22, 1994, Sunset Policy Statement said, in relevant part, that ''effective immediately, the Commission will presume, in the context of petitions to reopen and modify existing order in effect for more than twenty years.''[2] The Commission's consent order in Docket No. 7505 was issued on January 6, 1962, and has been in effect for thirty-years. Consistent with the Commission's July 22, 1994, Sunset Policy Statement, the resumption is that the order should be terminated. Nothing to overcome the presumption having been presented, the Commission has determined to reopen the proceeding and set aside the order in Docket No. 7505 as to respondent Rubber Manufacturers.

Accordingly, it is ordered That this matter be, and it hereby is, reopened;

It is further ordered, That the Commission's order in Docket No. 7505

[1] The remaining respondents did not petition the Commission to reopen and set aside the order as to them.

[2] See Sunset Policy Statement, 59 Fed. Reg. at 45,289.

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]

BILLING CODE 6750–01–M

[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

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

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