18. Part 804 is amended by revising the heading to read as set forth above.

19. Section 804.1 is amended by revising paragraph (a) to read as follows:

§ 804.1 Scope.

(a) FDA is requiring distributors of cigarettes or smokeless tobacco to report deaths, serious illnesses, and serious injuries that are attributed to contamination of a cigarette or smokeless tobacco product. Distributors of cigarettes or smokeless tobacco are also required to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that these products are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, distributors of cigarettes or smokeless tobacco are required to establish and maintain complaint files or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

* * * * *

20. Section 804.3 is amended by revising paragraph (d), and in paragraphs (m)(1) and (m)(2) by adding the phrase ''related to the contamination of cigarettes or smokeless tobacco'' after the word ''event'' to read as follows:

§ 804.3 Definitions.

* * * * *

(d) *Distributor* means, for the purpose of this part, any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption, but who does not repackage or otherwise change the container, wrapper, or labeling of the product package. Common carriers are not considered distributors for the purposes of this part.

* * * * *

§ 804.25 [Amended]

21. Section 804.25 *Reports by distributors* is amended in paragraph (a)(1) by removing the words ''a device'' and adding in their place the phrase ''contamination of a cigarette or smokeless tobacco product''; in paragraph (a)(2) by removing the phrase ''one of its marketed devices'' and adding in its place the phrase ''contamination of one of its cigarette or smokeless tobacco products''; and by removing paragraph (c).

Dated: May 1, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12614 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1240

[Docket No. 97P–0418]

Revocation of Lather Brushes Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulation pertaining to the treatment, sterilization, handling, storage, marking, and inspection of lather brushes. FDA is revoking this regulation because the regulation is no longer necessary to protect the public health.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Policy Development and Coordination Staff (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

DATES: This final rule is effective June 11, 1998.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 1997 (62 FR 54398), FDA proposed to revoke a regulation pertaining to the treatment, sterilization, handling, storage, marking, and inspection of lather brushes. The preamble to the proposal explained that the lather brush regulation was originally published in 1949 by the Federal Security Agency and was intended to prevent cases of cutaneous anthrax through lather brushes made from animal hair or bristles. A Government reorganization transferred the Federal Security Agency's functions to the then-Department of Health, Education, and Welfare (now known as the Department of Health and Human Services), and responsibility for the rule was later assigned, in 1975, to FDA. The rule was codified at § 1240.70 (21 CFR 1240.70).

FDA proposed to revoke the regulation because it was unaware of any reliance on the lather brush requirements or of any current concerns associated with lather brushes and because the regulation was no longer necessary to protect the public health. The proposal also noted that the then-Center for Disease Control (now the Centers for Disease Control and Prevention) revoked a similar lather brush regulation in 1985 on the grounds that no case of cutaneous anthrax in the United States had been associated with lather brushes since 1930.

FDA received no comments on the proposal. Consequently, this final rule revokes § 1240.70.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule eliminates certain manufacturing requirements for lather brushes, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Public Health Service Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1240 is amended as follows:

PART 1240—CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

§ 1240.70 [Removed]

2. Section 1240.70 *Lather brushes* is removed.

Dated: May 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12450 Filed 5–11–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–6011–6]

RIN 2060–AC19

National Emission Standards for Hazardous Air Pollutants for Source Categories; Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule: Amendments.

SUMMARY: This action promulgates final amendments to the National Emission Standards for Hazardous Air Pollutants for Source Categories; Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (SOCMI) by adding tetrahydrobenzaldehyde (THBA) and crotonaldehyde to, and removing acetaldol from, the list of chemical production processes. The amendment also establishes a separate compliance date of 3 years from final action for subparts F and G of part 63 and 1 year from final action for subpart H of part 63 for the THBA and crotonaldehyde production processes. The EPA is also making a change to clarify compliance demonstration requirements for flexible operation units.

This action implements section 112(d) of the Clean Air Act as amended in 1990 (the Act), which requires the Administrator to regulate emissions of hazardous air pollutants (HAP) listed in section 112(b) of the Act. The intended effect of this rule is to protect the public by requiring new and existing major sources to control emissions of HAP to the level reflecting application of the maximum achievable control technology. This action also amends the initial list of source categories of HAP required by section 112(c) of the Act by removing THBA production from the list of categories of major sources.

EFFECTIVE DATE: May 12, 1998.

FOR FURTHER INFORMATION CONTACT: For information concerning this action contact Mr. John Schaefer at (919) 541–0296, Organic Chemicals Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION:

I. Regulated Entities and Background Information

A. Regulated Entities

The regulated category and entities affected by this action include:

Category	Regulated entities
Industry ..	Facilities that produce tetrahydrobenzaldehyde; facilities that produce crotonaldehyde. Synthetic organic chemical manufacturing industry (SOCMI) units, e.g., producers of benzene, toluene, or any other chemical listed in Table 1 of 40 CFR part 63, subpart F.

This table is not intended to be exhaustive but, rather, provides a guide for readers regarding entities likely to be interested in the revisions to the regulation affected by this action. Entities potentially regulated by the HON are those which produce as primary intended products any of the chemicals listed in table 1 of 40 CFR part 63, subpart F or facilities producing THBA or crotonaldehyde and that are located at facilities that are major sources as defined in section 112 of the Clean Air Act (CAA). To determine whether your facility is regulated by this action, you should carefully examine all of the applicability criteria in 40 CFR 63.100. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

With today's action, EPA is making production of THBA and crotonaldehyde subject to subparts F, G, and H of 40 CFR Part 63. Subparts F, G, and H of 40 CFR Part 63 establish National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Synthetic Organic Chemical Manufacturing Industry (SOCMI) (57 FR 62607). This rule is commonly referred to as the hazardous organic NESHAP or the HON. The HON rule applies to SOCMI facilities located at major sources and affects approximately 310 facilities nationwide. These SOCMI facilities include those that produce one or more of the synthetic organic chemicals listed in Table 1 of Subpart F and that either (1) use an organic HAP as a reactant or (2) produce an organic HAP in the process. Emission points within these facilities affected by the rule are process vents, storage vessels, transfer operations, equipment leaks, and wastewater collection systems. Processes producing THBA were not included on the list of SOCMI processes to be regulated under the HON. Crotonaldehyde production was removed from the list of SOCMI processes to be regulated by the HON when the rule was issued in April 1994. Crotonaldehyde production was deleted because available information indicated that this chemical was no longer produced in the United States. Because EPA has since learned that crotonaldehyde is still produced in the United States, in today's action EPA is adding crotonaldehyde production to the HON.

II. Summary of Changes to Rule

A. Addition of THBA Production

Tetrahydrobenzaldehyde production was included as a source of HAP emissions under the source category of butadiene dimers production on the initial list of source categories selected for regulation under Section 112(c) of the Act published on July 16, 1992 (57 FR 31576) and was scheduled for control by November 1997 on the section 112(e) source category schedule (58 FR 63941). Although the initial source category list clearly identified THBA production as being included in the butadiene dimers production source category, the butadiene dimers name was a misnomer. Consequently, the butadiene dimers production source category was changed to tetrahydrobenzaldehyde production by a source category list maintenance action finalized on June 4, 1996 (61 FR 28197). Today's action will add THBA production to the list of HON-affected chemicals.

THBA is produced by reacting 1,3-butadiene and acrolein together. Both 1,3-butadiene and acrolein are HAPs