

indefinitely. This sentence reads as follows:

(j) "However, such raisins shall not be sold at a price below that which the committee concludes reflects the average price received by producers for free tonnage of the same varietal type purchased by handlers during the current crop year up to the time of any offer for sale reserve tonnage by the committee, to which shall be added the costs to the equity holders incurred by the committee on account of receiving, inspecting, storing, fumigating, insuring, and holding of said raisins, and including costs of taxes and interest: *Provided*, That, where the outlook for the next crop year or other factors have caused a downward trend in the prices received by producers for free tonnage raisins or in the prices received by handlers for free tonnage packed raisins, reserve tonnage may be sold to handlers at the currently prevailing or the approximate computed field price for free tonnage raisins, as determined by the committee."

(Secs. 1-19, 48 Stat. 31, as amended 7 U.S.C. 671-674)

Dated: June 1, 1984.

John Ford,  
Deputy Assistant Secretary Marketing and  
Inspection Services.

[FR Doc. 84-15152 Filed 6-4-84; 8:45 am]

BILLING CODE 3410-02-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 3

[Docket No. 84N-0079]

#### Labeling of Mouthwash, Mouth Freshener, and Gargle Preparations; Withdrawal of Proposed Statement of Policy

**AGENCY:** Food and Drug Administration.

**ACTION:** Withdrawal of proposed statement of policy.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing a proposed statement of policy setting forth labeling conditions for over-the-counter (OTC) mouthwash, mouth freshener, and gargle preparations. This action is taken as part of the agency's program to reconsider existing regulations and proposed rules on which final action has not been taken. The agency has reviewed this proposed regulation and determined that, because these products fall under a rulemaking

proceeding within the ongoing OTC drug review, this regulation is no longer necessary.

**FOR FURTHER INFORMATION CONTACT:** Eileen Hodkinson, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

**SUPPLEMENTARY INFORMATION:** In 1980, FDA began a program to reconsider existing rules and to withdraw outstanding proposed rules that have become obsolete because of the development of new technology, the passage of time, changes in agency priorities and policies, comments received, availability of regulatory alternatives that achieve the same consumer protection goals, or other reasons.

One such proposal that is outstanding was published in the *Federal Register* of August 4, 1970 (35 FR 12411), to set forth acceptable labeling for OTC mouthwash, mouth freshener, and gargle preparations. This proposal would have added a new section to Part 3, which subsequently was recodified into various parts of Subchapter C of Title 21 of the Code of Federal Regulations (40 FR 13996; March 27, 1975), to provide guidance to manufacturers and distributors in the preparation of labeling for these products.

Since 1972, however, the agency has been evaluating all currently marketed OTC drug products for safety and effectiveness under its OTC Drug Review Program. Through rulemaking procedures, the agency is establishing conditions under which OTC drug products will be considered generally recognized as safe and effective for their intended uses. These conditions, which included labeling, are being published for the various OTC drug categories in final monographs in the *Federal Register*. The advance notice of proposed rulemaking for OTC Oral Health Care Drug Products was published in the *Federal Register* of May 25, 1982 (47 FR 22760). When the final monograph for these products is published, it will cover OTC mouthwash drug products. In view of this OTC drug review rulemaking proceeding, the policy statement proposed in 1970 has been superseded and is no longer necessary.

Therefore, the proposed statement of policy published in the *Federal Register* of August 4, 1970 (35 FR 12411), is hereby withdrawn.

This withdrawal is issued under authority of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a)), 52

Stat. 1050-1053 as amended, 1055 (21 U.S.C. 352, 355, 371(a)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: May 29, 1984.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 84-14929 Filed 6-4-84; 8:45 am]

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#### 21 CFR Parts 3 and 131

[Docket No. 84N-0078]

#### Over-the-Counter Systemic Analgesics; Withdrawal of Proposed Statement of Policy and Changes in Warning Statements

**AGENCY:** Food and Drug Administration.

**ACTION:** Withdrawal of proposed statement of policy.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing a proposed statement of policy setting forth labeling conditions for over-the-counter (OTC) systemic analgesics. This action is taken as part of the agency's program to reconsider both existing regulations and proposed rules on which final action has not been taken. The agency has reviewed this proposed policy statement and has determined that, because these products fall under a rulemaking proceeding within the ongoing OTC drug review, this statement of policy is no longer necessary.

**FOR FURTHER INFORMATION CONTACT:** Eileen Hodkinson, Center for Drugs and Biologics (formerly National Center for Drugs and Biologics) (HFN-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

**SUPPLEMENTARY INFORMATION:** In 1980, FDA began a program to reconsider existing rules and to withdraw outstanding proposed rules that had become obsolete because of the development of new technology, the passage of time, changes in agency priorities and policies, comments received, availability of regulatory alternatives that achieve the same consumer protection goals, or other reasons.

One such proposal that is outstanding was published in the *Federal Register* of April 5, 1967 (32 FR 5560), to set forth acceptable labeling for OTC systemic analgesic. This proposal would have added a new section to Part 3, which subsequently was recodified into various parts of Subchapter C of Title 21 of the Code of Federal Regulations (40

FR 13996; March 27, 1975), to provide guidance to manufacturers and distributors in the preparation of labeling for these drug products.

Since 1972, however, the agency has been evaluating all currently marketed OTC drug products for safety and effectiveness under its OTC Drug Review Program. Through rulemaking procedures, the agency is establishing conditions under which OTC drug products will be considered generally recognized as safe and effective for their intended uses. These conditions, which include labeling, are being published for the various OTC drug categories in final monographs in the *Federal Register*. The advance notice of proposed rulemaking for OTC Internal Analgesic, Antipyretic, and Antirheumatic Drug Products was published in the *Federal Register* of July 8, 1977 (42 FR 35346). When the final monograph for these products is published, it will cover internal analgesic OTC drugs. In view of this OTC drug review rulemaking proceeding, the labeling policy statement concerning OTC systemic analgesics proposed in 1967 has been superseded and is no longer necessary.

Therefore, the proposed statement of policy published in the *Federal Register* of April 5, 1967 (32 FR 5560), is hereby withdrawn. This withdrawal is issued under authority of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 52 Stat. 1050-1053 as amended, 1055 (21 U.S.C. 352, 355, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10).

Dated: May 29, 1984.

Mark Novitch,  
*Acting Commissioner of Food and Drugs.*

[FR Doc. 84-14923 Filed 6-4-84; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[OAR-FRL-2601-71]

#### Approval and Promulgation of Implementation Plans; Ohio, Illinois, Indiana, and Michigan

**AGENCY:** Environmental Protection Agency (USEPA).

**ACTION:** Proposed rulemaking; correction.

**SUMMARY:** This notice provides additional information which should have been included in the proposed rulemaking on the approval and promulgation of implementation plans

for Ohio, Illinois, Indiana, and Michigan. This proposed rulemaking was published in the May 15, 1984, *Federal Register* (49 FR 20521).

**FOR FURTHER INFORMATION CONTACT:** Illinois: Randolph O. Cano, (312) 886-6035

Indiana: Robert Miller, (312) 886-6031  
Michigan: Toni Lesser, (312) 886-6037  
Ohio: Deborah Marcantonio, (312) 886-6088

Correction: In particular, on page 20521 on the May 15, 1984, *Federal Register* in the second column in the DATE section, the following words were omitted: "Comments on this revision and on the proposed USEPA action must be received by". Instead only the date June 14, 1984, was printed.

This paragraph should have read as follows: "**DATE:** Comments on this revision and on the proposed USEPA action must be received by June 14, 1984".

USEPA regrets any inconvenience that this omission has caused. The public comment period on this proposed rule will close June 14, 1984, as earlier intended. If this causes undue hardship, please contact the appropriate Region V staff member listed above and an alternative arrangement will be made.

Dated: May 25, 1984.

Valdas V. Adamkus,  
*Regional Administrator.*

[FR Doc. 84-14974 Filed 6-4-84; 8:45 am]

BILLING CODE 6560-50-M

### 40 CFR Part 61

[A-5-FRL 2600-2]

#### Designation of Areas for Air Quality Planning Purposes; Attainment Status Designation: Wisconsin

**AGENCY:** U.S. Environmental Protection Agency (USEPA).

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** USEPA proposes to revise the Total Suspended Particulates (TSP) designation for a sub-city area of Waukesha, Wisconsin, from primary/secondary nonattainment to just secondary nonattainment. This proposed revision is based on a redesignation request from the Wisconsin Department of Natural Resources (WDNR) and on supporting technical data submitted by the Department. Under the Clean Air Act (Act) attainment status designations can be changed if sufficient data are available to warrant such changes. The intent of this notice is to discuss the results of USEPA's review of the WDNR's redesignation request and their

supporting technical data, and to solicit public comment on the revision and on USEPA's proposed action.

**DATE:** Comments on this redesignation and on USEPA's proposed action must be received by July 5, 1984.

**ADDRESSES:** Copies of the redesignation request, the technical support documents, and the supporting air quality data are available at the following addresses:

Environmental Protection Agency,  
Region V, Air Programs Branch, 230 S. Dearborn Street, Chicago, Illinois 60604

Wisconsin in Department of Natural Resources, Bureau of Air Management, 101 South Webster, Madison, Wisconsin 53707

Comments on this proposed rule should be addressed to (Please submit an original and five copies, if possible):

Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), USEPA, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

**FOR FURTHER INFORMATION CONTACT:** Colleen W. Comerford, (312) 886-6034.

**SUPPLEMENTARY INFORMATION:** Under section 107(d) of the Act, the Administrator of USEPA has promulgated the National Ambient Air Quality Standards (NAAQS) attainment status for each area of Wisconsin. See 43 FR 8962 (March 3, 1978) and 43 FR 45993 (October 5, 1978). These area designations may be revised if sufficient data are available to warrant such changes.

#### Background

USEPA's criteria for Section 107 redesignations are summarized in two policy memorandums: (1) An April 21, 1983, policy memorandum from Sheldon Meyers, then Director of the Office of Air Quality Planning and Standards, entitled "Section 107 Designation Policy Summary"; and (2) a December 23, 1983, policy memorandum from G. T. Helms, Chief of the Control Programs Operation Branch, entitled "Section 107 Questions and Answers." In general, all available information relative to the attainment status of the area should be reviewed. In addition, a change from a primary nonattainment designation to a secondary nonattainment designation must be supported by:

(1) The most recent eight consecutive quarters of quality-assured, representative ambient air quality data which show no violations of the appropriate NAAQS, plus evidence of an implemented control strategy; and