U.S.C. 1828)" after the word "Act" the second place it is used.

(c) In § 5.50(g)(5), by inserting "(12 U.S.C. 1841)" after the word "Act."

Dated: November 24, 1981.

Charles E. Lord,

Acting Comptroller of the Currency.

[FR Doc. 81-34892 Filed 12-3-81; 8:45 am]

BILLING CODE 4810-33-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 523

[No. 81-723]

Liquidity

Dated: November 25, 1981.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: This amendment increases the investment flexibility of Federal Home Loan Bank member institutions by authorizing them to invest for liquidity in obligations issued by the National Credit Union Administration.

EFFECTIVE DATE: November 25, 1981.

FOR FURTHER INFORMATION CONTACT: David J. Bristol, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW. Washington, D.C. 20552, (202) 377-6461.

SUPPLEMENTARY INFORMATION: Section 5A of the Federal Home Loan Bank Act, as amended ("Bank Act") (12 U.S.C. 1425(a)), provides that Federal Home Loan Bank member institutions may invest for liquidity purposes in obligations of the United States or any of its political subdivisions, agencies or instrumentalities, as the Board may approve.

The Board's liquidity regulation at 12 CFR 523.10(f) provides general eligibility for obligations of the United States issued by agencies or instrumentaries thereof and fully guaranteed as to principal and interest by the United States. While the Comptroller General of the United States has ruled that obligations that the National Credit Union Administration ("NCUA") issues on behalf of its Central Liquidity Facility are obligations of an independent agency of the executive branch, he also has ruled that such obligations are not backed by the full faith and credit of the United States. For this reason, it is necessary to specifically refer to NCUA in paragraph (g) of § 523.10, along with other agencies whose obligations are not backed by full faith and credit, e.g. obligations of the Federal National Mortgage Association.

The Board's decision to authorize NCUA obligations as liquid assets is based on its belief that a liquid market for such obligations will soon develop, and the Board's desire to further implement provisions of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 (Pub. L. 95-630) encouraging savings and mortgage lending and to provide maximum flexibility for investment by member institutions. The Board therefore has determined to amend subparagraph (g)(3) of § 523.10 to allow investment for liquidity purposes in obligations issued by NCUA, subject to applicable maturity limitations. The Board notes that this amendment will automatically be incorporated by reference into 12 CFR 545.9(a) which authorizes Federal associations to invest in liquid assets, other than time deposits and bankers' acceptances, without regard to maturity, and that no additional amendment to § 545.9 is necessary to facilitate investment in such obligations by Federal associations.

Because the Board believes that this amendment will relieve investment restrictions, thereby providing greater investment flexibility for Federal associations and other Federal Home Loan Bank member institutions, the Board finds that observance of the notice and comment procedures of 12 CFR 508.11 and 5 U.S.C. 553(b) and the 30-day delay of effective date provision of 12 CFR 508.14 and 5 U.S.C. 553(d) is unnecessary and contrary to the public interest, and the amendment therefore will become effective as provided above.

Accordingly, the Board hereby amends Part 523 of Subchapter B, Chapter V of Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER B—REGULATIONS FOR THE FEDERAL HOME LOAN BANK SYSTEM

PART 523—MEMBERS OF BANKS

Liquidity

Amend § 523.10(g)(3) by removing the word "or" at the end of subdivisions (x) and (xi), and by adding a new subdivision (xiii) thereto, to read as follows:

§ 523.10 Definition for purposes of this section, §§ 523.11 and 523.12.

* * * * *

(g) *Liquid assets.* * * *

(3) Obligations with five years or less remaining until maturity, issued, or fully guaranted as to principal and interest, by:

* * * * *

(xiii) the National Credit Union Administration;

* * * * *

(Federal Home Loan Bank Act, 5A, 12 U.S.C. 1425a; Reorg. Plan No. 3 of 1947, 3 CFR 1071 (1943-48 Comp. p. 1071)

By the Federal Home Loan Bank Board.

J. J. Finn,

Secretary.

[FR Doc. 81-34933 Filed 12-3-81; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Medical Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to add an express redelegation of authority to officials in the Bureau of Medical Devices regarding determinations of the effectiveness of medical devices. The authority delegated is a clarification of the authority previously delegated to the Bureau.

EFFECTIVE DATE: November 25, 1981.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: Section 5.53 (21 CFR 5.53), initially published in the **Federal Register** of August 2, 1977 (42 FR 39100), authorizes the Bureau of Medical Devices to approve, disapprove, or withdraw approval of applications for premarket approval of medical devices submitted under sections 515 and 520(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e and 360j(1)) with no restrictions. The agency has found that the delegation of authority in § 5.53 is subject to misinterpretation because of the wording of the law in section 513(a)(3)(B) of the act (21 U.S.C. 360c(a)(3)(B)) which permits authorization of determinations of effectiveness of medical devices to be made based on evidence other than evidence derived from well-controlled investigations by qualified experts. That section also is applicable to section 515 of the act, but the delegation of authority in § 5.53 does not clearly identify the fact that the authorization authority of

section 513(a)(3)(B) of the act is a part of the authority delegated. To clarify that the authority of the Bureau to approve applications for premarket approval includes this separate authority under section 513 of the act, a new delegation of authority is being issued in new § 5.49 (21 CFR 5.49). This section expressly redelegates to the Bureau the authority to authorize determinations of effectiveness based on evidence other than well-controlled investigations.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis.

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly § 5.1; see 46 FR 26052; May 11, 1981)), Part 5 is amended by adding § 5.49 to read as follows:

§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The Director, the Deputy Director, and the Associate Director for Device Evaluation of the Bureau of Medical Devices, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act.

Effective date. This regulation is effective November 25, 1981.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: November 25, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-34788 Filed 12-1-81; 10:55 am]

BILLING CODE 4160-01-M

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21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of D&C Green No. 6; Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Green No. 6 for use as a color additive in externally applied drugs and cosmetics. The new closing date will be January 30, 1982. This brief postponement will provide time for determining the applicability of the statutory standard for the listing of color additives to the results of scientific investigations of D&C Green No. 6.

EFFECTIVE DATE: Effective December 1, 1981, the new closing date for D&C Green No. 6 will be January 30, 1982.

FOR FURTHER INFORMATION CONTACT: Garnett R. Higginbotham, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: The current closing date of December 1, 1981, for the provisional listing of D&C Green No. 6 was established by a regulation published in the **Federal Register** of September 29, 1981 (46 FR 47533). This closing date for D&C Green No. 6 was established to provide time for completion of FDA's review and evaluation of the data concerning the external uses of D&C Green No. 6, for determining the applicability of the statutory standard for the listing of color additives to D&C Green No. 6, and for publication of a regulation in the **Federal Register** regarding the final decision on the petition for the permanent listing of this color additive. The regulation set forth below will postpone the December 1, 1981 closing date for the provisional listing of the color additive until January 30, 1982.

The review and evaluation of the data relevant to the use of D&C Green No. 6 in externally applied drugs and cosmetics and the decision about how to apply the statutory standard for the listing of color additives to such data have required more time than anticipated. FDA concludes that the brief extension of the closing date to January 30, 1982, is necessary. The agency has also concluded that no harm to the public health will result from this extension.

Because of the shortness of time until the January 30, 1982 closing date, FDA concludes that notice and public procedure on this regulation are impracticable, and that good cause exists for issuing this postponement as a final rule.

This regulation will permit the uninterrupted use of the color additive until further action is taken. In accordance with 5 U.S.C. 553 (b) and (d) (1) and (3), this postponement is issued as a final regulation and is being made effective on December 1, 1981.

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

§ 81.1 [Amended]

Therefore, under the Transitional Provisions of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act (Title II, Pub. L. 86-618, sec 203, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 81 is amended in § 81.1 *Provisional lists of color additives,* by revising the closing date for "D&C Green No. 6" in paragraph (b) to read "January 30, 1982."

Effective date. This regulation is effective December 1, 1981.

(Sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note))

Dated: November 19, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 81-34683 Filed 11-30-81; 11:55 am]

BILLING CODE 4160-01-M

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21 CFR Part 173

[Docket No. 80F-0365]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Epichlorohydrin-Ammonia Crosslinked Copolymer, Quarternized With Methyl Chloride

Corrections

In FR Doc. 81-33154 appearing on page 57032 of the issue of Friday, November 20, 1981, make the following corrections:

On page 57033, first column, the twenty-second line reading "petition and order relevant material and" should read "petition and other relevant material and".

On the same page, second column, last paragraph, the effective date should be "November 20, 1981".

BILLING CODE 1505-01-M

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21 CFR Part 178

[Docket No. 81F-0011]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers; Dibenzylidene Sorbitol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of dibenzylidene sorbitol as a clarifying agent for certain olefin polymers that are articles or components of articles intended to contact food. This action is in response to a petition filed on behalf of Milliken and Co.

DATES: Effective December 4, 1981, objections by January 4, 1982.

ADDRESS: Written objections to the Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julia L. Ho, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 20, 1981 (46 FR 13376), FDA announced that a food additive petition (FAP 1B3541) had been filed on behalf of Milliken and Co., Inman, SC 29334, proposing that the food additive regulations be amended to provide for the safe use of dibenzylidene sorbitol as a clarifying agent for certain olefin polymers intended for use as articles or components of articles intended to contact food.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting that finding, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 178 is amended in Subpart D by adding new § 178.3295, to read as follows:

§ 178.3295 Clarifying agents for polymers.

Clarifying agents may be safely used in polymers that are articles or components of articles intended for use in contact with food, subject to the provisions of this section:

Substances	Limitations
Dibenzylidene sorbitol (CAS Reg. No. 32647-67-9) formed by the condensation of two moles of benzaldehyde with one mole of sorbitol, such that the final product has a minimum content of 95 percent dibenzylidene sorbitol.	For use only as a clarifying agent for olefin polymers complying with § 177.1520(c) 1.1, 3.1, and 3.2 of this chapter under conditions of use C, D, E, F, and G, described in Table 2 of § 176.170(c) of this chapter at a level not exceeding 0.25 percent by weight of the polymer.

Any person who will be adversely affected by the foregoing regulation may at any time on or before January 4, 1982 submit to the Dockets Management Branch, address above, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective December 4, 1981.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: November 25, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-34789 Filed 12-3-81 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 808

[Docket No. 77N-0333]

Exemption From Preemption of State and Local Hearing Aid Requirements; Applications for Exemption; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule on the District of Columbia's application for exemption from preemption for its hearing aid requirements. This action is necessary to correct an inconsistency between the preamble to the final rule and the rule itself.

EFFECTIVE DATE: December 4, 1981.

FOR FURTHER INFORMATION CONTACT: Les Weinstein, Bureau of Medical Devices (HFK–143), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7114.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 10, 1980 (45 FR 67326), FDA issued a final rule on the application for exemption from preemption for the District of Columbia's hearing aid requirements. Section 5 of Act 2–79 of the District of Columbia is preempted by section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)). In the preamble to the final rule, FDA stated its intention to grant an exemption from preemption for the section to the extent that it requires an audiological evaluation for children under the age of 18. Section 808.101(b) (21 CFR 808.101(b)), however, inadvertently provided that FDA denied an exemption from preemption for the entire section. This document corrects § 808.101 to make it consistent with the preamble and with FDA's decisions concerning similar provisions of other State statutes. As corrected, § 808.101 reads as follows:

§ 808.101 District of Columbia.

(a) The following District of Columbia medical device requirements are enforceable, notwithstanding section 521 of the act, because the Food and Drug Administration has exempted them from preemption under section 521(b) of the act:

(1) Act 2–79, section 5, to the extent that it requires an audiological evaluation for children under the age of 18.

(2) Act 2–79, section 6, on the condition that in enforcing section 6(a)(5), the District of Columbia apply

the definition of "used hearing aid" in § 801.420(a)(6) of this chapter.

(b) The following District of Columbia medical device requirement is preempted by section 521(a) of the act, and the Food and Drug Administration has denied it an exemption from preemption under section 521(b) of the act: Act 2-79, section 5, except as provided in paragraph (a) of this section.

Dated: November 25, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-34694 Filed 12-3-81; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF-96; Re: Notice No. 360]

Sonoma Valley Viticultural Area; Establishment

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in Sonoma County, California, named "Sonoma Valley." The Bureau of Alcohol, Tobacco and Firearms (ATF) believes the establishment of the Sonoma Valley viticultural area and the subsequent use of its name as an appellation of origin on wine labels and in wine advertisements will help consumers to identify the wines from this distinctive grape-growing area. The use of this viticultural area as an appellation of origin will also help winemakers distinguish their products from wines made in other areas.

EFFECTIVE DATE: January 4, 1982.

FOR FURTHER INFORMATION CONTACT: John A. Linthicum, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226 (202 566-7602).

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF-53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definite viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements. Section 4.25a(e)(1) defines an American viticultural area as a delimited grape-growing region distinguishable by geographical features. Section 4.25a(e)(2) outlines procedures for proposing an American viticultural area.

In response to a petition, ATF published a notice of proposed rulemaking in the **Federal Register** on December 15, 1980 (45 FR 82470), proposing the Sonoma Valley viticultural area in Sonoma County, California. ATF solicited written comment and held a public hearing on the proposal on January 13, 1981, in Santa Rosa, California.

ATF received several comments relating to Sonoma Valley among the numerous comments relating to the five viticultural areas proposed in Notice No. 360. All of the comments relating to Sonoma Valley were generally in favor of establishment of the Sonoma Valley viticultural area. Some commenters submitted additional historical evidence relating to the name.

Historical Evidence

The Sonoma Valley viticultural area has a long history of grape growing and wine making. In 1825, the first grapes were planted in Sonoma at the Mission San Francisco de Solano. In 1834, General Mariano Guadalupe Vallejo expanded these plantings. In the 1850's, the first major plantings of *Vitis vinifera* in the United States were established in the Sonoma Valley area. By 1900, there were approximately 4,000 acres of vines in the Sonoma Valley. The area has continued to be a center for grape production and wine making. Thus, ATF feels the viticultural area meets the requirement of 27 CFR 9.3(b)(1) that the name of the viticultural area is locally or nationally known as referring to the area specified in the viticultural area proposal.

Several persons testified at the public hearing that the proposed boundaries reasonably delineate the area historically known as "Sonoma Valley." Based on the record of the rulemaking proceedings, ATF feels that the boundaries described in 27 CFR 9.29 delineate the area historically known as Sonoma Valley, as required by 27 CFR 9.3(b)(2).

Geographical Features

Under 27 CFR 9.3(b)(3), a viticultural area must possess geographical features which distinguish the viticultural features of the area from surrounding areas. Based on the record, ATF believes that the Sonoma Valley viticultural area is distinguishable from the surrounding areas because of its climate.

The viticultural area, located in the southeastern corner of Sonoma County, receives less rainfall than other portions of Sonoma County north of the city of Santa Rosa. In addition, the Sonoma Mountains, ranging along the western border of the viticultural area, prevent the heavy fog often found in the area of Petaluma from intruding into most of the Sonoma Valley area. These same mountains along with the Mayacamas Range on the eastern boundary of the viticultural area geographically isolate the area from surrounding areas. This geographical isolation and the proximity of the San Pablo Bay on the southern end of the area combine to moderate the summer and winter temperature extremes in the valley.

Boundaries

Much of the hearing testimony was on the proposed boundaries with controversy arising over the boundaries in the northeastern and southeastern corners of the viticultural area. One vineyard owner felt that the northeastern corner of the Sonoma Valley viticultural area should be part of a future viticultural area which he planned to propose. He stated that he did not object, however, to the proposed Sonoma Valley boundaries as long as the approval of the boundary would not preclude a future viticultural area from partially overlapping that corner of the Sonoma Valley viticultural area. ATF does not object to a proposed viticultural area solely on the grounds that it may partially overlap another area. Each area must be judged individually on the criteria required in the regulations. Each area must meet the same requirements concerning the area's proposed name and the presence of distinguishing geographical characteristics. In addition, the establishment of viticultural areas is an evolutionary process. ATF will continue to consider any new information concerning viticultural areas. The boundary in the northeast corner of the Sonoma Valley viticultural area is drawn along the peaks of the mountains surrounding Sonoma Valley. ATF feels that this boundary delineates an area which meets the requirements for a viticultural area. This area includes the area traditionally known as Sonoma Valley and which possesses generally similar geographical features which distinguish it from the surrounding areas.

The boundary in the southeastern corner of the viticultural area was controversial because it conflicted with the previously proposed Napa Valley viticultural area by including a small