(2) The column 1 rate of duty applicable to item 121.61 of the TSUS is modified to read "5% ad val." effective as to articles entered or withdrawn from warehouse for consumption on and after October 30, 1982.

Pursuant to section 604 of the Trade Act (19 U.S.C. 2483), modifications of TSUS item numbers and article descriptions made by Proclamation 4694 will remain in effect until terminated or modified by subsequent action. Pursuant to section 125(e) of the Trade Act (19 U.S.C. 2135(e)), the current column 1 rate of duty applicable to TSUS item 107.48 will, unless some earlier action is taken with regard thereto, remain in effect until October 30, 1983, at which time it will revert to 7.5% ad valorem.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-ninth day of October, in the year of our Lord nineteen hundred and eighty-two, and of the Independence of the United States of America the two hundred and seventh.

Ronald Reagan

[FR Doc. 82-30272
Filed 11-1-82; 10:45 am]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 47, No. 212
Tuesday, November 2, 1982

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 273 and 282

[Amdt. No. 206]

Food and Stamp Program: Removal of Certain References and Demonstration Project Pre-Operational Procedures From the Code of Federal Regulations

Correction

In FR Doc. 82-28484, appearing at page 46485, in the issue of Tuesday, October 19, 1982, make the following changes:

On page 46486, in the second column, § 273.9(d)(4) the first line should read "(d) *Dependent care.* Payments for the".

BILLING CODE 1505-01-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 563

[No. 82-710]

Surety Bonds

Dated: October 27, 1982.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: The Federal Home Loan Bank Board ("Board") is amending its regulation pertaining to maintenance of fidelity bond coverage for officers and employees of institutions the accounts of which are insured by the Federal Savings and Loan Insurance Corporation ("insured institutions"), to permit the boards of directors of insured institutions to adopt riders as they may deem appropriate. As a result of these amendments, an institution's board of directors will obtain greater flexibility to add riders negotiated with or required by underwriters without prior Board approval.

EFFECTIVE DATE: October 27, 1982.

FOR FURTHER INFORMATION CONTACT: Peter M. Barnett, Associate General Counsel (202-377-6445), or Cynthia D. Farmer, Legal Assistant (202-377-6472), Office of the General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW. Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION: On January 18, 1979, the Board adopted amendments to its regulations governing surety bond coverage required to be maintained by insured institutions (12 CFR 563.19 and 571.14) to change the maximum deductible amounts permitted for fidelity bonds of insured institutions and codify the Board's policy regarding acceptable surety companies. FHLBB Resolution No. 79-31; 44 FR 4936 (January 24, 1979). These amendments permitted negotiation between an insured institution and a surety company within regulatory limitations designed to prevent unsafe and unsound practices and allowed a deductible not exceeding 2 percent of an insured institution's net worth with an exception for smaller institutions. These amendments also reduced the requirements for approval of surety companies, thereby increasing competition and encouraging better rates and services to insured institutions.

Currently, questions regarding the acceptability of insurance policy riders which may result in coverage different from that specified in § 563.19(a) are handled at the supervisory level. From this experience, the Board believes that choices regarding specific bond coverage, within the guidelines set forth in Standard Form No. 22, can safely be made by the management of individual institutions. Therefore, in order to provide broad guidelines for these institutions and in order to ensure the enforceability of surety bond requirements, the Board is revising the language in § 563.19.

Because this amendment is a rule of Board procedure and relieves institutions of the burden of seeking Board approval before accepting riders to surety bonds, the Board finds it is unnecessary to publish general notice of proposed rulemaking pursuant to 12 CFR 508.13 and 5 U.S.C. 553(b) or to delay publication of the amendment for the period of time specified in 12 CFR 508.14 and 5 U.S.C. 553(d).

List of Subjects in 12 CFR Part 563

Savings and loan associations.

Accordingly, the Board hereby amends Part 563 of Subchapter D, Chapter V of Title 12, *Code of Federal Regulations*, as set forth below.

PART 563—OPERATIONS

Revise the text preceding the chart in paragraph (a) of § 563.19, as follows:

§ 563.19 Bonds for directors, officers, employees, and agents; form of and amount of bonds.

(a) Each insured institution shall maintain bond coverage with a bonding company acceptable to the Corporation, using the standards set out in § 571.14 of this Subchapter, in the form known as Standard Form No. 22 or its equivalent. The bond shall cover each director, officer, employee and agent who has control over or access to cash or securities of such institution. Such coverage shall be maintained in the minimum amount set forth below, computed on a base consisting of the total assets of the institution plus the unpaid balance of loans which it has contracted to service for others. The institution's board of directors must specifically approve any riders to Standard Form 22 and the approval of any rider must be set forth in the minutes of the meeting at which the board of directors approves that rider.

* * * * *

(Sec. 407, 48 Stat. 1260, as amended; 12 U.S.C. 1730, Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943-48 Comp., p. 1071)

By the Federal Home Loan Bank Board.

J. J. Finn,
Secretary.

[FR Doc. 82-30150 Filed 11-1-82; 8:45 am]

BILLING CODE 6720-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB-49]

Staff Accounting Bulletin No. 49

AGENCY: Securities and Exchange Commission.

ACTION: Publication of Staff Accounting Bulletin.

SUMMARY: This staff accounting bulletin expresses the staff's views regarding disclosures by bank holding companies about loans to public and private sector borrowers located in countries that are experiencing liquidity problems.

DATE: October 26, 1982.

FOR FURTHER INFORMATION CONTACT: Marc D. Oken or Edmund Coulson, Office of the Chief Accountant (202/272–2130); or Howard P. Hodges, Jr. or Charles A. Oglebay, Jr., Division of Corporation Finance (202/272–2553), Securities and Exchange Commission, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION: The statements in Staff Accounting Bulletins are not rules or interpretations of the Commission nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

George A. Fitzsimmons,

Secretary.

October 26, 1982.

Staff Accounting Bulletin No. 49

The staff herein adds Section H to Topic 11 of the Staff Accounting Bulletin Series. This section discusses the disclosures by bank holding companies about loans to foreign countries that are experiencing liquidity problems.

Topic 11: Miscellaneous Disclosure

* * * * *

H. *Disclosures by Bank Holding Companies About Certain Foreign Loans.*

Facts:

Periodically, certain foreign countries experience political and economic conditions which create liquidity problems. These conditions may have a material impact on the ability of both private and public sector borrowers in these countries to make timely principal or interest payments on obligations to U.S. banks. Although these factors may be separate and apart from the normal credit risks of international lending activities, they potentially affect the ability of borrowers to comply with the terms of their lending agreements because it may be difficult to obtain U.S. dollars or other foreign currency necessary to service these cross border obligations currently.

Because of the significant conversion risks and other uncertainties related to these loans, many bank holding companies have been providing certain disclosures about them in Commission filings. However, the nature of these disclosures has varied significantly and numerous questions have arisen with respect to the staff's views on the appropriate disclosures in these circumstances.

Question:

What disclosures does the staff view as appropriate when a bank holding company has cross border loans to foreign countries that are currently experiencing liquidity problems?

Interpretive Response:

Bank holding companies engaged in cross border lending activities in countries experiencing liquidity problems may be faced with unusual risks or uncertainties. The staff believes that information about such situations is material to investors because it is necessary to assist them in making judgments about international lending activities which involve more than normal credit risks. This view is consistent with the Commission's long-standing requirement that registrants include in both Securities Act and Securities Exchange Act filings "such further material information as is necessary to make the required statements, in light of the circumstances under which they are made, not misleading." [1] Further, the requirements of Industry Guide 3, "Statistical Disclosures by Bank Holding Companies," provide that separate disclosure of loan categories be given when a substantial portion of loans are concentrated in one or a few foreign countries or to show any other unusual risks or uncertainties.[2]

The staff believes that the following disclosures represent the appropriate minimum information which is necessary in Securities Act or Securities Exchange Act filings to inform investors about the possible impact of cross border lending transactions on the registrant. For purposes of this guidance, the one percent criterion has been arbitrarily selected in the interest of facilitating disclosure.[3]

1. Where conditions in a country give rise to problems which may have a material impact on the timely payment of interest or principal on that country's private or public sector debt, and where the aggregate outstandings (loans, acceptances, interest-bearing deposits with other banks and other investments) related to such country which are payable to the registrant in U.S. dollars or other foreign currencies exceed one percent of the registrant's total consolidated outstandings, the country should be identified.

2. The amount of such outstandings to all identified countries should be stated in absolute dollars, as a percentage of total amounts, or in a similar manner which will indicate the magnitude of the outstandings related to the identified countries. While the amount of the outstandings may be aggregated, where the aggregate amount so disclosed comprises heavy concentrations in any country, the amount related to that country should be separately disclosed.

3. An indication as to the effect that these conditions have had or are expected to have on the financial condition or results of operations of the registrant should be provided.

As an alternative to the above disclosures, the following information may be provided:

1. Identify each country in which the total private and public sector outstandings which are payable to the registrant in U.S. dollars or other foreign currencies exceed one percent of the registrant's total consolidated outstandings.

2. The amount of outstandings to each such identified country should be stated in absolute terms, as a percentage of total amounts, or in a similar manner which will indicate the magnitude of the outstandings related to the identified country.

3. If the outstandings to any of the identified countries have had or are expected to have a material adverse impact on the registrant's financial condition or results of operations, this impact should be discussed.

[FR Doc. 82-30145 Filed 11-1-82; 8:45 am]

BILLING CODE 8010-01-M

[1] 17 CFR 230.408 and 17 CFR 240.12b–20.

[2] Industry Guide 3, Section III.A.

[3] The one percent referred to in the following text is for the purpose of disclosure guidance, not as an indicator of a prudent level of lending to any one country by an individual bank.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74, 81, and 82

[Docket No. 76C-0045]

D&C Green No. 5; Listing as a Color Additive in Drugs and Cosmetics; Termination of Stay and Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; termination of stay and confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is terminating the stay of regulation for the "permanent" listing of D&C Green No. 5 for use in drugs and cosmetics, excluding use in the area of the eye. The regulation was stayed by the filing of objections under the formal rulemaking provisions of the Federal Food, Drug, and Cosmetic Act while FDA evaluated and acted on the objections. The agency has completed its evaluation of the objections and concludes that they are not adequate to continue the stay of the regulation listing D&C Green No. 5. Therefore, this document terminates the stay of the regulation and confirms the effective date of July 7, 1982, for the regulation listing D&C Green No. 5 for general use in drugs and cosmetics, excluding use in the area of the eye. This document also amends the color additive regulations by removing D&C Green No. 5 from the color additive provisional list.

DATE: Effective date confirmed: July 7, 1982.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, 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 November 1, 1982, for the provisional listing of D&C Green No. 5 was established by a final regulation published in the **Federal Register** of September 3, 1982 (47 FR 38883). The date was set to provide FDA time to evaluate and act on objections received in response to a final regulation published in the **Federal Register** of June 4, 1982 (47 FR 24285), that approved a petition for the permanent listing of D&C Green No. 5 for general use in drugs and cosmetics, excluding use in the area of the eye. The preamble to the September 3, 1982 final rule announced that the regulation that permanently listed D&C Green No. 5 for drug and cosmetic use was stayed pending final agency action on the objections.

The agency received two letters stating objections to the permanent listing regulation for D&C Green No. 5. One objection was from an individual, and one was from a consumer group. The objections are on file in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, under the docket number found in the heading of this document. No requests for a hearing, however, were received in response to the listing regulation.

After evaluating the two objections, the agency finds that neither presents issues of fact that warrant a hearing (21 CFR 12.24(B)). The objections and the agency's response to them are summarized below.

1. One objection focused on the conclusion of the Board of Scientific Counselors (the Board) of the National Toxicology Program (NTP) that "in male mice [in the bioassay of D&C Green No. 5 sponsored by the Cosmetic, Toiletry, and Fragrance Association (CTFA)], there was a small but statistically significant increase in combined hepatocellular carcinomas and hepatocellular adenomas based on pairwise comparison and trend analysis." The objection noted that on the basis of cumulative biological factors, FDA decided that CTFA's test results are negative for carcinogenicity. The objection argued, however, that the Board concluded that the data are equivocal, and argued that, therefore, "there is sufficient concern that the dye is a carcinogen and unsafe" to require the FDA not permanently list this color additive.

The agency's reasons for concluding that the carcinogenicity bioassays for D&C Green No. 5 are negative are fully explained in the preamble to the June 4, 1982 final rule. FDA incorporates by reference herein all discussions of this issue set forth in the preamble to the final rule.

Although it is true, as the objection states, that the Board concluded that the data are equivocal, it is also true that the Board attributed the equivocality to the statistical results. The members of the Board pointed to certain limitations in the data available to them and suggested certain additional analyses that could possibly resolve the equivocality. For example, Dr. Breslow, the statistical consultant to the Board, stated that he had two reservations about his statistical analysis of the data. First, he noted that the results for the high-dose group could have been the result of expected variability in the data. Therefore, he suggested that FDA perform an analysis of variance on the data:

> Dr. Breslow: Well, let me raise a question about it and perhaps it will come up again later. The question is has anyone actually analyzed this data to look at the within versus the between experiment, components of variability and historical incidence? And secondly, the degree to which that is in excess of the binomial expected variability?
>
> Dr. Moch: The answer is no.
>
> Dr. Breslow: It would be very helpful, I think, if that were done.

Transcript of March 9, 1982 Meeting of Board of Scientific Counselors, NTP (Tr.), 34–35.

He also stated that his analysis took no account of the plausibility of any of the biological mechanisms. Tr. 96. Doubts about the statistical analysis were also expressed by the consulting pathologist to the Board (Ref. 1), who pointed out that the biological evidence failed to substantiate the trend analysis.

FDA will endeavor to resolve any equivocality in data presented to it to assure that the agency's regulatory decisions are as well-informed and as fair as possible. Of course, in the interest of the public health and safety, FDA will not approve a petition for a color additive if the agency is unable to conclude that safe conditions of use can be established on the basis of the evidence before it. In the case of D&C Green No. 5, FDA focused on the two factors mentioned by Dr. Breslow in the agency's effort to resolve the equivocality that the Board found.

The first factor FDA considered was the import of the incidence of hepatocellular tumors in the control and test groups in the male mouse D&C Green No. 5 bioassay. Before the Board met, FDA had counted the tumors and found that 11 of the 56 mice (19.6 percent) in the high-dose (2 percent of diet) treatment group had hepatocellular tumors. Tumor incidence in the concurrent control groups was much lower. Only 4 of 59 animals (6.8 percent) in one control group and 6 of 59 (10.2 percent) in the other had hepatocellular tumors. In addition, in the lowest dose group (0.05 percent of diet), only 2 of 57 animals (3.5 percent) had tumors. On the basis of these results, the p-value for the dose-related trend for these neoplasms is low.

Upon review of the historical data, however, the agency found that the average (mean) spontaneous incidence among historical controls at Hazleton Laboratories was 18.7 percent (59 of 316 animals). (See Attachment 4 to the Summary Minutes of the March 9, 1982 meeting of the Board of Scientific Counselors, NTP.) Thus, the incidence of hepatocellular tumors in the high-dose group is virtually the same as the average incidence in the historical controls. This fact caused FDA, and later the Board, to question whether the low p-value found for dose-related trend for hepatocellular neoplasms reflected a real biological effect.

Further analysis was necessary before FDA could determine what effect the historical control data had on the importance of the statistical results. Therefore, after the Board met, as Dr.

Breslow suggested, FDA conducted an analysis of variance on the incidence of liver neoplasms in male mice of the CD–1 strain used at Hazleton Laboratories as controls in other studies. The purpose of this analysis was to determine whether the incidence of hepatocellular tumors in the high-dose treatment group is significantly higher than the spontaneous background incidence.[1]

This analysis revealed that the tumor incidence in the D&C Green No. 5 high-dose group is within the expected range for controls. On the basis of this analysis, FDA has concluded that the tumor incidence found in the high-dose group is attributable to random variation. This conclusion mitigates the significance of the low p-value calculated using the concurrent control groups. Based on the foregoing, FDA ascribes the low p-value in the trend test to the low incidence of tumors in the concurrent control and low-dose groups rather than to a treatment-related increase in the incidence of tumors in the high-dose group.

Turning to the question of the biological mechanism, the agency found that the analysis of the microslides of the mouse livers did not reveal the progressive development in the tumors that would be expected of a carcinogenic effect (see 47 FR 24282; June 4, 1982). As FDA stated in the preamble to the June 4, 1982 final rule, in the test of D&C Green No. 5, the characteristics of the liver tumors were similar in both the treated and control groups. These findings have led FDA to conclude that the small increase in incidence of liver tumors in the high-dose group was a spurious and nonreproducible occurrence. *ID.*

In summary, FDA believes that, in this instance, the p-value calculated using the concurrent controls for the trend in the incidence of hepatocellular tumors in the mouse bioassay of D&C Green No. 5 is not a crucial factor in determining whether this bioassay has shown the color additive to be a carcinogen. The agency has evaluated the biological and historical, as well as the statistical, data from the mouse bioassay of D&C Green No. 5. On the basis of its evaluation of all the relevant data, FDA finds that, contrary to the objection, the mouse bioassay, like the rat bioassay, of D&C Green No. 5 was negative rather than positive or equivocal.

2. Both objections stated opposition to the final rule permanently listing D&C Green No. 5 on the basis of the Delaney Clause of the Color Additive Amendments of 1960 (the Amendments). The objections contended that the presence of *p*-toluidine in D&C Green No. 5 (referred to as a mixture of chemicals by one of the objections) is evidence that the color additive as a whole causes cancer, and that for that reason, FDA must deny the petition. The objections also contended that the Delaney Clause is an absolute prohibition of the approval of any color additive that causes cancer in animals or man. Both objections cited 21 U.S.C. 321 (section 201 of the Federal Food, Drug, and Cosmetic Act (the act)) in support of their argument that D&C Green No. 5 is subject to the Delaney Clause because it contains *p*-toluidine. These objections were not accompanied by new information.

For the scientific and legal reasons that were fully explained in the June 4, 1982 listing regulation, and are incorporated here by reference, the agency disagrees with the interpretation of the Amendments (21 U.S.C. 376) in the objections.

FDA no longer believes that it must refuse to list a color additive because that additive contains or is expected to contain a carcinogenic impurity. The agency interprets the Delaney Clause as applying when tests of the color additive as a whole indicate that the substance causes cancer. It is true that this interpretation represents a departure from some of the agency's previous actions under the Amendments. However, an agency can change its position when, as here, it gives reasons for the change, and when no egregious injustice results. *Public Citizen* v. *Foreman*, 631 F. 2d 969, 976 n. 15 (D.C. Cir. 1980).

Contrary to the assertion in one of the objections, as discussed in the final rule on D&C Green No. 6 (47 FR 14138, 14142; April 2, 1982) (Ref. 2), which the agency incorporated in the D&C Green No. 5 decision (47 FR 24280; June 4, 1982), FDA believes that its interpretation is consistent with the language and intent of the Delaney Clause. Section 706 of the act (21 U.S.C. 376) prescribes a system for regulating substances called "color additives", which the statute distinguishes from the intermediates and other impurities that these substances contain. The statute specifically states that the impurities and intermediates contained in a color additive should be considered in determining whether use of the color additive is safe. 21 U.S.C. 376(b)(5)(A)(iv)(I). However, it makes no mention of these impurities and intermediates in the Delaney Clause. In this section, the statute speaks only of the color additive. 21 U.S.C. 376(b)(5)(B). Therefore, FDA believes that the Delaney Clause should be interpreted, in line with its literal terms, as requiring the ban of only those color additives that have been found to cause cancer in an appropriate test of the additive as a whole.

FDA agrees that, because the starting materials in a chemical reaction are never completely reacted, the color additive is likely to contain residual amounts of its starting materials. D&C Green No. 5, therefore, may contain small amounts of D&C Green No. 6, which in turn is likely to contain small amounts of one of its own starting materials, *p*-toluidine, a carcinogen. In addition, the agency agrees that the presence of *p*-toluidine could be cause for concern if it is present at high enough levels, but FDA does not agree that the color additive is unsafe under the Delaney Clause.

The Delaney Clause states that a color additive shall be deemed unsafe and shall not be listed.

> * * * For any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal * * *.

21 U.S.C. 376(b)(5)(B)(i). D&C Green No. 5 has been appropriately tested for ingested uses. In the chronic toxicity studies, it was fed to rats at exaggerated dietary levels of up to 1.0 percent and to mice at levels of up to 2.0 percent. These studies are of good quality in design and execution and meet contemporary standards of toxicological sensitivity. On the basis of the chronic toxicity studies, FDA has concluded that, under the conditions of these tests, D&C Green No. 5 does not induce cancer, and that therefore the Delaney Clause is not a bar to the permanent listing of this color additive.

The Delaney Clause does not require FDA to ban an additive on the hypothesis that the additive might cause cancer if it were tested in a hypothetical study. As discussed in the D&C Green No. 6 final rule (47 FR 14142), the agency believes that any risk to the public health presented by the presence of *p*-toluidine in D&C Green No. 5 is appropriately and adequately regulated under the general safety clause. 21 U.S.C. 376(b)(4).

3. One objection cited the statistically significant increase in hepatocellular tumors observed in the high dose group of male mice in the D&C Green No. 5 bioassay and argued that it "seems

[1] The use of appropriate historical control data as an aid in evaluating data on a given chemical is a well-established practice. See, e.g., NCI Technical Report No —.

plausible that there is an association between the known carcinogenicity of *p*-toluidine and the evidence of carcinogenicity of D&C Green No. 5."

FDA disagrees with the objection for two reasons. First, as discussed in response to comment 1 above, FDA has concluded that the incidence in tumors in male mice receiving the high dose of the color additive was not a carcinogenic effect of D&C Green No. 5. Therefore, there is no basis for associating the carcinogenicity of *p*-toluidine with the observed increase in liver tumors in the D&C Green No. 5 bioassay. Second, in the *p*-toluidine study, mice were fed *p*-toluidine at a dosage level of 100 milligrams per kilogram body weight per day, whereas the mice in the D&C Green No. 5 study were exposed to *p*-toluidine from contamination at a level of 0.003 milligram per kilogram body weight per day. Thus, there was a 30,000-fold difference in the level of exposure to *p*-toluidine in the two studies. Contrary to the objection, it is not plausible that the number of hepatocellular tumors in the high-dose group is attributable to the presence of *p*-toluidine in D&C Green No. 5 because *p*-toluidine is a relatively weak carcinogen, as was demonstrated in the Weisburger Study (47 FR 24279; June 4, 1982 (footnote 1)).

4. One objection claimed that a risk between 1 in 30 million and 1 in 300 million provides a reasonable certainty of some harm rather than a reasonable certainty of no harm as is stated in the regulation. This objection argued that, in a population the size of the United States, it is likely that someone will have cancer as a result of exposure to D&C Green No. 5.

FDA disagrees. The objection's conclusion reflects a misunderstanding of the risk assessment that FDA performed and of the meaning and use of upper limit risk estimates in determining whether a substance is safe. An upper limit risk assessment, such as that performed by FDA, does not predict with mathematical precision what will actually occur. Indeed, such an assessment is intended to overestimate rather than to underestimate the potential risk and establishes a worst-case estimate of the results from exposure to the substance.

As explained in the final rule (47 FR 24284; June 4, 1982), FDA calculates the upper limit of risk from a lifetime exposure to the regulated uses of D&C Green No. 5 to be no greater than 1 additional case of cancer in 30 million people (or 1 in 300 million using the alternate method of risk assessment cited in the final rule (47 FR 24284)). This estimate does not mean, as the objection asserts, that 1 person in 30 million (or 1 in 300 million) will inevitably contract cancer. It does mean that the agency can conclude with reasonable certainty that no more than 1 person in 30 million (or 1 in 300 million) will contract cancer from exposure to D&C Green No. 5. The worst-case risk estimate is consistent with the likelihood that no cancers will result from the use of this color additive and thus with a reasonable certainty of no harm.

Therefore, the agency disagrees with the objection and concludes that the claim made in the objection is without merit.

5. Both objections asserted that FDA's reliance on *Monsanto* v. *Kennedy* (613 F. 2d 947 (D.C. Cir. 1979)) is misplaced. One objection argued that the *Monsanto* decision did not authorize the agency to disregard the policy expressed in the Delaney Clause. The other objection argued that *Monsanto* is not dispositive of the issues here, and that even if it is, neither prong of the *Monsanto* exception is met here. This objection argued that FDA has not found that the amount of *p*-toluidine in D&C Green No. 5 is de minimis, or that the color additive presents no health or safety concerns.

FDA disagrees with each of these assertions.

First, the agency does not believe that it is disregarding the Delaney Clause. In drafting the Delaney Clause, Congress implicitly recognized that known carcinogens might be present in color additives as intermediates or impurities but at levels too low to trigger a response in conventional test systems. Congress apparently concluded that the presence of these intermediates or impurities at these low levels was acceptable. This legislative judgment accounts for the absence of any requirement in the Delaney Clause that the impurities and intermediates in a color additive, rather than the additive as a whole, be tested or otherwise evaluated for safety. Thus, Congress drew a rough, quantitative distinction between a color additive that is deemed unsafe under the Delaney Clause because it causes cancer, and an additive that is not subject to the Delaney Clause because it does not cause cancer even though one of its constituents does. FDA's decision on D&C Green No. 5 is consistent with this distinction.

Second, FDA does not believe that this matter can be distinguished from *Monsanto* v. *Kennedy*, as one objection attempts to do. Even though *Monsanto* involved a contaminant that migrates to food from a container, and this rulemaking involves a contaminant that is directly added to ingested drugs and cosmetics as part of a color additive, both matters are concerned with the regulation of such contaminants under the act. Consequently, *Monsanto* is directly relevant to the issues present here. (See 47 FR 14145; April 2, 1982 and 47 FR 24280; June 4, 1982.)

Third, it is true that FDA did not explicitly make the findings required by *Monsanto* in the D&C Green No. 5 decision. However, that decision incorporates the D&C Green No. 6 final rule, in which the agency stated:

> * * * FDA has determined that in finished drugs and cosmetics containing D&C Green No. 6 the amount of *p*-toluidine is so small, and the risks from its use are so insignificant, that no public health or safety concerns are presented. Therefore, it is appropriate to grant the petition to list D&C Green No. 6.

47 FR 14145.

There is almost 100 times more *p*-toluidine in D&C Green No. 6 than there is in D&C Green No. 5. This fact, plus the fact that, according to FDA's calculations, the upper limit individual lifetime risk from exposure to *p*-toluidine as a result of use of products containing D&C Green No. 6 (1 in 15 million) is almost twice as great as the upper limit risk from exposure to *p*-toluidine as a result of use of products containing D&C Green No. 5 (1 in 30 million), clearly establish that the level of *p*-toluidine in finished drug and cosmetic products containing D&C Green No. 5 is so negligible that it presents no public health or safety concerns.

6. One objection stated that D&C Green No. 5 contains lead and arsenic, which are known carcinogens. The objection made this claim as a further contention that the final listing regulation for this color additive is in violation of the Delaney Clause.

The specifications for D&C Green No. 5, as published in the **Federal Register** of June 4, 1982 under 21 CFR 74.1205(b)(2), establish maximum tolerances for lead at 20 parts per million and for arsenic at 3 parts per million. FDA did not include these specifications to permit the addition of lead or arsenic to the color additive. The agency established these specifications because it recognizes that lead and arsenic are ubiquitous in the environment (see 21 U.S.C. 346), and that there are limits on a manufacturer's ability to assure that these impurities will not get into a batch of a color additive. Therefore, the agency has set forth the limits on the amount of heavy metals that it will accept in the certification process. FDA will not certify a sample that exceeds these specifications. Thus, these specifications

assure that the color additive will be safe under its conditions of use.

If FDA interpreted the Delaney Clause as forbidding approval of any color additive that contains a carcinogenic impurity, FDA would be unable to approve any color additive because practically no additive can be made so as to exclude low levels of lead and arsenic. Similarly, the Delaney Clause, if interpereted as the objector suggests, would bar approval of many food additives because they also may contain low levels of lead and arsenic. Certainly, Congress did not intend that the Delaney Clause would operate to ban all these additives simply because they contain, at low levels, recognized carcinogenic substances like lead and arsenic.

Based on the foregoing, it is clear that the specifications for lead and arsenic in D&C Green No. 5 do not present any reason for invoking the Delaney Clause.

7. One objection stated that FDA had failed to consider that there are color additives, proven to be safe, that could be substituted for D&C No. 5 for use in drugs and cosmetics.

FDA has no legal authority under the act to consider the presence or lack of other suitable color additives in determining whether to regulate a color additive. The criterion for evaluation has been, and remains, safety.

Conclusion

The agency has completed its evaluation of the objections and concludes, for the reasons discussed in this document, that the objections are not adequate to stay the regulations listing D&C Green No. 5 as a color additive. No requests for a hearing were received in response to the listing regulation. Therefore, this document terminates the stay of the regulations and confirms the effective date of July 7, 1982, for the regulations listing D&C Green No. 5. With the listing of D&C Green No. 5, the entries for this color additive under 21 CFR Part 81 are now obsolete.

Therefore, the agency also concludes that the entries for D&C Green No. 5 should be removed from 21 CFR 81.1 and 81.27. The agency concludes that there is good cause not to provide for further public comment on this change in the regulation. The change is a mere editorial revision to remove D&C Green No. 5 from the provisional list, because of the November 1, 1982 expiration of the closing date for provisional listing, and because of this document that confirms the effective date of the permanent listing regulation.

References

The following information has been placed in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Letter of Stan D. Vesselinovitch to Larry G. Hart, Assistant to the Director, NTP, April 8, 1982.

2. Final Rule on D&C Green No. 6 (47 FR 14138; April 2, 1982).

List of Subjects in 21 CFR Parts 74, 81, and 82

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c) and (d))) and the Transitional Provisions of the Color Additive Amendments of 1960 (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), 21 CFR Chapter I is amended as follows:

1. The stay of effectiveness of §§ 74.1205, 74.2205, and 82.1205 is terminated.

2. Part 81 is amended as follows:

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

§ 81.1 [Amended]

1. In § 81.1 *Provisional lists of color additives*, paragraph (b) is amended by removing the entry "D&C Green No. 5".

§ 81.27 [Amended]

2. In § 81.27 *Conditions of provisional listing*, paragraph (d) is amended by removing the entry "D&C Green No. 5".

Effective date. July 7, 1982.

(Sec. 706(b), (c) and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: October 28, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-30061 Filed 10-28-82; 3:52 pm]

BILLING CODE 4160-01-m

---

21 CFR Parts 74, 81, and 82

[Docket No. 82N-0268]

D&C Orange No. 5

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is permanently listing D&C Orange No. 5 for use in lipsticks or other lip cosmetics and in drug and cosmetic mouthwashes and dentifrices. This action is a partial response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA). This final rule will remove D&C Orange No. 5 from the provisional list of color additives. However, to provide an opportunity for objections, published elsewhere in this issue of the **Federal Register** is an order that extends the closing date for the provisional listing of D&C Orange No. 5 for use in lipsticks and other lip cosmetics and in drug and cosmetic mouthwashes and dentifrices. In addition, that order terminates the provisional listing of this color additive for use in externally applied drugs and cosmetics. This final rule also cancels certificates for D&C Orange No. 5 for use in externally applied drugs and cosmetics.

DATES: Effective November 30, 1982; objections by November 29, 1982; Certificates cancelled effective October 29, 1982.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1973 (38 FR 21199), FDA announced that a petition (CAP 6C0041) for the permanent listing of D&C Orange No. 5 as a color additive for general use in drugs and cosmetics had been filed by the Toilet Goods Association, Inc. (now CTFA, c/o Hazleton Laboratories, Inc., 9200 Leesburg Turnpike, Vienna, VA 22180). The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

In the **Federal Register** of October 12, 1960 (25 FR 9759), as amended August 16, 1961 (26 FR 7578), and December 30, 1970 (35 FR 19749), FDA established temporary tolerances under § 81.25 (21 CFR 81.25), formerly § 8.503 (21 CFR 8.503), for the use of certain provisionally listed color additives, including D&C Orange No. 5, in lipsticks, ingested drugs, and other products subject to ingestion, such as mouthwashes and dentifrices. The agency set tolerance limits because "subacute studies have established that these colors are toxic substances, unsafe