racing and associated equipment under § 12.85(c)(6) is adopted, with the addition that this period may be extended at the discretion of the district director of Customs for one or more additional periods, not to exceed a total of 3 years. The other changes to § 12.85 are adopted as proposed.

**Lists of Subject in 19 CFR Part 12**

Customs duties and inspection, Imports, Importers, Marine safety.

**Regulations Amendments**

## PART 12—SPECIAL CLASSES OF MERCHANDISE

Section 12.85, Customs Regulations [19 CFR 12.85], is amended as follows:

**§ 12.85 Coast Guard boat and associated equipment safety standards. [Amended]**

1. Section 12.85(c)(1) is amended by removing the last sentence.

2. Section 12.85(c)(4) is amended by removing "60 days" and inserting "1 year" wherever it appears.

3. Section 12.85(c)(4) is further amended by removing the last sentence.

4. Section 12.85(c)(6) is amended by revising it to read as follows:

* * * * *

(c) * * *

(6) *Certain products entered for tests, experiments, exhibits, or races.* An importer or consignee seeking to enter a product for period not to exceed 1 year, for tests, experiments, exhibits, or races but not for sale in the United States, shall file a declaration in accordance with paragraph (d) of this section. The declaration shall state that the importer or consignee is importing the product solely for the stated purpose and that it will not be sold or operated in the United States, unless the operation is an integral part of the stated use for which the product was imported. The importer or consignee shall attach to the declaration a description of use for which the product is being imported, the time period estimated for completion, and disposition to be made of the product after completion. Entry under this paragraph may be authorized for a period not to exceed 1 year from the date of importation. However, this period may be extended at the discretion of the district director for one or more additional periods which, when added to the initial 1-year period, shall not excceed a total of 3 years.

5. Section 12.85(d) is amended by revising it to read as follows:

* * * * *

(d) *Declaration requirements.* All declarations submitted must:

(1) Be filed at the time of entry, in duplicate on Form CG–5096.

(2) Be signed by the importer or consignee.

(3) State the name and U.S. address of the importer or consignee.

(4) State the entry number and date.

(5) Provide the make, model, and hull identification number, if affixed, or date of manufacture if hull identification number not affixed, of any boat, and a description of any equipment or component.

(6) Identify, if known, the city or state in which the product will be principally located.

(7) Be sent by the district director, to the Commandant (G–BBS–1/42), U.S. Coast Guard, Washington, D.C. 20593.

* * * * *

6. Section 12.85(e)(2) is amended by revising it to read as follows:

* * * * *

(e) *Release under bond.*

(1) * * *

(2) *Time limitation to produce statement for which bond is obligated.* Within 180 days after entry, the importer or consignee shall deliver to both the district director and the Commandant, U.S. Coast Guard, a copy of the statement for production of which the bond was obligated. If the statement is not delivered to the district director for the port of entry of the product within 180 days after the date of entry, the importer or consignee shall deliver or cause to be delivered to the district director the product that was released in accordance with this paragraph.

* * * * *

(R.S. 251, as amended, secs. 623, 624, 46 Stat. 759, as amended, secs. 5, 6, 7, 11, 15, 85 Stat. 215, 216, 217, 219 (5 U.S.C. 301; 19 U.S.C. 66, 1623, 1624; 46 U.S.C. 1454, 1455, 1456, 1460, 1464) 49 CFR 1.46(n) (1))

**Executive Order 12291**

This document does not meet the criteria for a "major rule" as specified in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

**Regulatory Flexibility Act**

It is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the rule will not have a significant economic impact on a substantial number of small entities.

**Drafting Information**

The principal author of this document was Jesse V. Vitello, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices and the Coast Guard participated in its development.

**Alfred R. De Angelus,**

*Acting Commissioner of Customs.*

Approved: November 1, 1982.

**John M. Walker, Jr.,**

*Assistant Secretary of the Treasury.*

Approved:

**J. S. Gracey,**

*Commandant, United States Coast Guard.*

[FR Doc. 82–31755 Filed 11–18–82; 8:45am]

BILLING CODE 4820–02–M

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**19 CFR Part 111**

**[T.D. 82–219]**

## Customs Regulations Amendment Relating to Discharge of an Importer's Liability for Duties

**AGENCY:** U.S. Customs Service, Treasury.

**ACTION:** Final rule.

**SUMMARY:** Customs recently published a final rule in the **Federal Register** which provided an alternative procedure for an importer of record to pay duties on imported merchandise through a licensed customhouse broker. That document required brokers to provide a written notification to their clients that if they elect to pay by check, they may pay Customs charges with a separate check payable to the "U.S. Customs Service." One method of notification involves providing the written statement to each active client annually during the month of February beginning February 1983, and during each February thereafter. An active client is defined to mean a client from whom a broker has obtained a power of attorney. Because the notification procedure and definition of active client may create unintended burdensome results, this document amends the Customs Regulations to alleviate these burdens by providing that (1) the broker shall provide the notification statement to each active client annually beginning no later than February 28, 1983, and at least once at any time within each subsequent 12-month period thereafter; and (2) an active client means a client from whom a broker has obtained a power of attorney and for whom the broker has transacted Customs business on at least two occasions within the 12-month period preceding notification.

**EFFECTIVE DATE:** December 20, 1982.

**FOR FURTHER INFORMATION CONTACT:**

Legal Aspects: Edward B. Gable, Jr., Office of Regulations and Rulings (202–566–5706)

Operational Aspects: Herbert H. Geller, Duty Assessment Division (202–566–5307), U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229

**SUPPLEMENTARY INFORMATION:**

**Background**

On July 27, 1982, Customs published a final rule in the **Federal Register** (T.D. 82–134; 47 FR 32416) which provided an alternative procedure for an importer of record to pay duties on imported merchandise through a licensed customhouse broker. When an importer uses a broker and pays by check or bank draft, the importer often furnishes the broker one check or bank draft covering both duties and the broker's fees and charges. The broker then pays the duties to Customs on behalf of the importer. Under the alternative procedure, the importer may elect to submit to the broker a separate check or bank draft for the duties, payable to the "U.S. Customs Service." The broker would then deliver the importer's check or bank draft to Customs.

That document also required brokers to provide a written notification to their clients advising that if the clients are importers of record, payment to the brokers will not relieve the clients of liability for Customs charges in the event the charges are not paid by the brokers. Clients also are advised that if they elect to pay by check, they may pay Customs charges with a separate check payable to the "U.S. Customs Service," which shall be delivered to Customs by the broker. Under T.D. 82–134, brokers are required to provide this information statement on, or attached to, a power of attorney executed on or after September 27, 1982. Additionally, brokers are required to provide the statement to each active client annually during the month of February beginning in February 1983, and during each February thereafter. The rule also defined an active client to mean a client from whom a broker has obtained a power of attorney.

It has been brought to Customs attention that the requirement to notify clients during the month of February and the definition of active client are creating unintended burdensome results.

For example, brokers already may send written communications to clients under their present procedures concerning various accounting, reconciliation, and relating matters. At that time, which may occur other than during the month of February, brokers could provide clients with the information statement. Customs has no objection to when the notification is given, provided there is written notification at least once within a 12-month period. Accordingly, to alleviate an unintended paperwork burden on brokers, this document amends the first sentence of § 11.29(b)(2)(ii), Customs Regulations (19 CFR 111.29(b)(2)(ii)), to provide that brokers shall provide the information statement to each active client annually beginning no later than February 28, 1983, and at least once at any time within each subsequent 12-month period thereafter.

In a related matter, Customs has determined that the definition of an active client is too restrictive. There may be accounts from whom a broker has obtained a power of attorney but for whom the broker has not transacted Customs business often or within a recent period of time. Accordingly, to further alleviate a burden on brokers, this document amends the second sentence of § 111.29(b)(2)(ii), Customs Regulations, to provide that an active client means a client from whom a broker has obtained a power of attorney and for whom the broker has transacted Customs business on at least two occasions within the 12-month period preceding notification.

**Executive Order 12291**

This document does not meet the criteria for a "major rule" as specified in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

**Regulatory Flexibility Act**

It is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the rule will not have a significant economic impact on a substantial number of small entities.

**Inapplicability of Public Notice Requirement**

The amendments are minor, of particular interest only to a limited segment of the general public, and relieve a burden on that segment. Therefore, pursuant to 5 U.S.C. 552(b)(B), notice and public participation are considered to be unnecessary.

**Drafting Information**

The principal author of this document was Charles D. Ressin, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

**List of Subjects in 19 CFR Part 111**

Customs duties and inspection, Imports, Brokers.

**Amendment to the Customs Regulations**

Part 111, Customs Regulations (19 CFR Part 111), is amended as set forth below.

**Alfred R. De Angelus,**

*Acting Commissioner of Customs.*

Approved: November 1, 1982.

**John M. Walker, Jr.,**

*Assistant Secretary of the Treasury.*

## PART 111—CUSTOMHOUSE BROKERS

Section 111.29(b)(2)(ii), Customs Regulations, is revised to read as follows:

**§ 111.29 Diligence in correspondence and paying monies.**

* * * * *

(b) *Notice to client of method of payment.* * * *

(2) Brokers shall provide the information statement in paragraph (b)(1) as follows:

(ii) To each active client no later than February 28, 1983, and at least once at any time within each subsequent 12-month period thereafter. An active client means a client from whom a broker has obtained a power of attorney, and for whom the broker has transacted Customs business on at least two occasions within the 12-month period preceding notification.

* * * * *

(R.S. 251, as amended, secs. 624, 641, 46 Stat. 759, as amended, 77A Stat. 14; (5 U.S.C. 301, 19 U.S.C. 66, 1202 (Gen. Hdnte. 11), 1624, 1641))

[FR Doc. 82–31829 Filed 11–18–82; 8:45 am]

BILLING CODE 4820–02–M

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**19 CFR Part 144**

**[T.D. 82–204]**

## Customs Regulations Amendments Relating to Customs Bonded Warehouses

*Correction*

IN FR Doc. 82–29742, beginning on page 49355, in the issue of November 1, 1982, on page 49376, in the third column, Appendix A, paragraph 1., *"Agreement to secure against loss."*, the eighth line which now reads "including an expense caused by", should read "including an expense caused by the transfer of merchandise or".

BILLING CODE 1501–01–M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 74, 81, and 82**

**[Docket No. 82N-0299]**

## FD&C Green No. 3

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is "permanently" listing FD&C Green No. 3 for use in food, drugs, and cosmetics, except for use in the area of the eye. This action is in response to a petition filed by the Cosmetic, Toiletry, and Fragrance Association; the Pharmaceutical Manufacturers Association; and the Certified Color Manufacturers Association, Inc. This rule will remove FD&C Green No. 3 from the provisional list of color additives for use in food, drugs, and cosmetics. Published elsewhere in this issue of the **Federal Register** is an order extending the closing date for the provisional listing of FD&C Green No. 3 until February 14, 1983.

**DATES:** Effective December 16, 1982; objections by December 15, 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:** Blondell Anderson, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

FD&C Green No. 3 is a water soluble color additive of the triphenylmethane class. It is used to color food, including candy, beverages, dessert powders, and ice cream and sherbet; ingested drugs; lipsticks; and externally applied cosmetics.

FD&C Green No. 3 is principally *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide, inner salt disodium salt (CAS Reg. No. 2353-45-9).

The Color Additive Amendments of 1960 (the amendments) require FDA premarket clearance of any color additive that is intended to be used or that is represented for use in or on food, drugs, certain medical devices, cosmetics, or the human body. Under the amendments, a use of a color additive may be approved and listed if there are sufficient data establishing that the color additive is safe for its intended use.

Recognizing that many color additives were already in use at the time it enacted the amendments, Congress established transitional provisions to allow for the provisional listing and continued use of these color additives for a period of time necessary to complete the scientific investigations needed to evaluate the safety of these substances under the standards prescribed in the amendments.

Section 81.1 of the color additive regulations (21 CFR 81.1) identifies those color additives that are provisionally listed under section 203(b) of 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 sets forth the closing date for each color additive. The closing date is the last day upon which a provisionally listed color additive can be used legally, absent an approval of a color additive petition and the permanent listing of the substance by FDA. (See section 203(a)(1) of the Transitional Provisions.)

FD&C Green No. 3 has been provisionally listed for use in food, drugs, and cosmetics since the enactment of the amendments. During that time, a series of toxicological studies have been performed on this color additive. Based upon the evaluation of the results of these studies and other pertinent data, the agency has concluded that FD&C Green No. 3 is safe for use in food, drugs, and cosmetics, except use in the area of the eye. Therefore, FDA is listing FD&C Green No. 3 for these uses.

### II. Regulatory History of FD&C Green No. 3

FDA announced in a notice in the **Federal Register** of November 20, 1968 (33 FR 17205) that a petition (CAP 8c0065) for the listing of FD&C Green No. 3 as a color additive for general use in food, drugs, and cosmetics had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry, and Fragrance Association (CTFA)); the Pharmaceutical Manufacturers Association (PMA); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, Inc. (CCMA)), c/o Hazleton Laboratories of America, Inc., 9200 Leesburg Turnpike, Vienna, VA 22180. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376). A subsequent notice published in the **Federal Register** of March 5, 1976 (41 FR 9584), amended the notice of filing for this petition to include the additional use of FD&C Green No. 3 in cosmetics intended for use in the area of the eye (Docket No. 76C-0043).

Regulations published in the **Federal Register** of February 4, 1977 (42 FR 6992), required new chronic toxicity studies for FD&C Green No. 3 as a condition of its continued provisional listing for ingested uses because the studies conducted previously were not adequate under current standards. As a result of those regulations, the agency postponed the closing date for the provisional listing of the color additive for both ingested and external uses until January 31, 1981, for completion of the studies.

In the **Federal Register** of March 27, 1981 (46 FR 18958), the agency established a new closing date of November 16, 1982, for the complete evaluation of FD&C Green No. 3. When the order set forth below becomes effective, it will remove FD&C Green No. 3 from the provisional list. Published elsewhere in this issue of the **Federal Register** is an order extending the closing date for the provisional listing of FD&C Green No.3 until February 14, 1983, to provide the opportunity for the filing of objections to this order.

### III. Evaluation of the Safety of FD&C Green No. 3 for Food, Drug, and Cosmetic Use

A. *Statutory safety requirement.* Under section 706(b)(4) of the act (21 U.S.C. 376(b)(4)), the so-called "general safety clause" for color additives, a color additive cannot be listed for a particular use unless the data presented to FDA establish that the color is safe for that use. Although what is meant by "safe" is not explained in the general safety clause, the legislative history makes clear that this word is to have the same meaning for color additives as for food additives. (See H. Rep. No. 1761, "Color Additive Amendments of 1960," Committee on Interstate and Foreign Commerce, 86th Cong., 2d Sess. 11 (1960).) The Senate report on the Food Additives Amendment of 1958 states:

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.
>
> This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of

scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

S. Rep. No. 2422, "Food Additives Amendment of 1958," Committee on Labor and Public Welfare, 85th Cong., 2d Sess. 6 (1958).

FDA has incorporated this concept of safety into its color additive regulations. Under 21 CFR 70.3(i), a color additive is "safe" if "there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." Therefore, the general safety clause prohibits approval of a color additive if doubts about the safety of the additive for a particular use are not resolved to an acceptable level in the minds of competent scientists.

B. *Safety studies on FD&C Green No. 3.* In reviewing food and color additive petitions, FDA routinely reviews all data submitted to it by the petitioner. The agency also reviews any other pertinent data that may be available to it. The agency's review includes consideration of the appropriateness of the data, of the methods used for their evaluation, and of the conclusions drawn from them. On the basis of this review, the agency makes an independent scientific judgment on whether the additive is safe. The examination of the data for FD&C Green No. 3 by FDA scientists revealed some instances of incorrect interpretation of the data in the petition, as discussed further below.

To establish that FD&C Green No. 3 is safe for use in food, drugs, and comestics, the petitioners have submitted reports on a number of animal toxicity studies for the color additive. Among these studies are acute toxicity studies (mice and rats); 2-year chronic feeding toxicity studies (rats, dogs, and mice); metabolism studies (rats, dogs, and rabbits); dermal studies (rabbits and mice); carcinogenicity by subcutanceous injection studies (rats, 1 and 2 years); a test for cathartic activity (dogs); and a primary irritation and sensitization study (guinea pigs). These studies did not produce any evidence that the use of this color additive, for the petitioned uses, would be unsafe.

However, as stated above, in 1977 the agency required that additional chronic toxicity studies be conducted. As a result, CCMA sponsored two additional studies on FD&C Green No. 3: a lifetime feeding study in mice and a lifetime feeding study following in utero exposure to the color additive in rats. The studies were conducted by Bio/dynamics, Inc., East Millstone, NJ (the testing laboratory). FDA received the final reports for these studies on November 16, 1981. In analyzing the data from these studies, the testing laboratory noted a possible treatment-related effect on the urinary bladders of male rats. Consequently, CCMA, for the petitioners, decided to have a histopathologic evaluation done on all urinary bladders from male rats, including the bladders from the low- and mid-dose groups, which had not previously been examined. CCMA arranged to have these data reviewed by a consulting pathologist. The petitioners submitted the results of these evaluations as an addendum on February 19, 1982.

Charles River CD–1 mice were used for one of the chronic feeding toxicity and carcinogenicity studies with FD&C Green No. 3. Five test groups were established, receiving the color additive at dietary levels of 0 percent (2 control groups), 0.5 percent, 1.5 percent, or 5.0 percent for 733 to 737 days. Sixty males and 60 females were randomly selected for each group. There was no evidence of any treatment-related increase in the incidence of neoplasms at any site in either male of female treated mice.

The long-term feeding study in rats included in utero exposure to FD&C Green No. 3. Sixty males and sixty females of Charles River CD rats ($F_o$), randomly selected for each group, were fed the color additive at dietary levels of 0 percent (2 control groups), 1.25 percent, 2.5 percent, and 5.0 percent. The parental ($F_o$) animals received the color additive starting approximately 2 months before mating. From each of the parental ($F_o$) dosage groups listed above, i.e., 0, 1.25, 2.5, and 5.0 percent, 70 $F_1$ rats of each sex were randomly selected for the chronic feeding study at the same dosage levels. The duration of the feeding period was 29 and 31 months for males and females, respectively.

The statistical analyses performed for the petitioners by the testing laboratory reported *p*-values from trend tests for small increases in tumor incidence in the liver, testes, and thyroid that supported possible associations with treatment. The agency discovered, however, in its review of the data that the petitioners submitted on FD&C Green No. 3 that the petitioners had not used the correct statistical procedures in analyzing this data. The petitioners had employed non-incidental time adjusted analyses in their statistical review of the data. These analyses incorporate the assumption that the tumors caused the death of the animals shortly after their appearance, but the tumors in the rat bioassay of FD&C Green No. 3 were not lethal. Therefore, FDA statisticians reanalyzed the data using incidental time adjusted analyses (Ref. 1). These reanalyses produced *p*-values that were substantially higher than those found by the petitioners.

The incidental (prevalence) analysis gave a *p*-value of $p=0.062$ for the high dose to combined control group comparison for the incidence of combined hepatocellular carcinomas and neoplastic nodules of the liver in male rats. For a bioassay of this size, this *p*-value reflects an unremarkable finding. Nevertheless, agency pathologists examined the incidences of all proliferative lesions of hepatocytes, including foci of cellular alteration, to be better able to judge, overall, whether there was a neoplastic process in the liver associated with treatment. They found the incidence of these pre-neoplastic lesions to be comparable across treatment and control groups, thus providing reassurance that there is no effect on male rat livers attributable to FD&C Green No. 3.

The high dose to combined control comparison (prevalence) for the incidence of benign interstitial cell (Leydig) tumors of the testes gave a *p*-value of $p=0.040$. In groups originally containing 70 animals, 12 rats were observed with this tumor in the high dosage group compared to 6 in each control group. Agency scientists have concluded, however, that these results do not reflect a treatment-related effect. There were two main reasons for this conclusion. First, these benign tumors are commonly observed in old age rats at quite variable spontaneous rates. For example, in a study of the safety of FD&C Blue No. 2 performed with the same strain of rats, at the same laboratory, and at the same time as the FD&C Green No. 3 study, the incidence of testicular tumors in the 2 control groups was 13 and 14 rats, exceeding the 12 rats with this tumor observed in the high dosage group of the FD&C Green No. 3 study. Second, in the low dosage group in the FD&C Green No. 3 study, 10 rats were observed with this tumor even though the testes of only 27 animals were examined microscopically. Even if microscopic examination of the remainder turned up no additional testicular tumors, which is unlikely, the number of tumor-bearing rats in this group would be nearly comparable to that in the high dosage group. If FD&C Green No. 3 was acting as a tumerigen to the male rat testis, the fourfold increase in dose between the low and high dosage levels should have produced a substantial increase in tumor incidence in the high dose. It did not.

Finally, because of, among other factors, the difficulty in distinguishing

tumor types, the statistical analysis of thyroid tumors should have been performed on combined incidences of carcinomas and adenomas, not merely on carcinomas, as was done by the testing laboratory. When the tumors are combined, the direct comparison between the high dosage group and the combined control groups gives a $p$-value of $p > .3$. Even when only the incidence of carcinomas is considered, the $p$-value for the comparison between the high dose and combined control groups is $p = .065$, an unremarkable finding.

For these reasons, FDA has concluded, contrary to the original laboratory report, that there was no significance to the reported differences in tumor incidence in the liver, testes, or thyroid.

The petitioners' submission of November 16, 1981, also indicated that the testing laboratory had found that there had been an increase in the incidence of bladder neoplasms in the high-dose male group. The original submission reported that this increase was statistically significant. However, in the addendum to the final report submitted by the petitioners on February 19, 1982, the testing laboratory reported that this increased incidence was not statistically significant. In addition, the petitioners' consulting pathologist independently reviewed all microslides of the urinary bladder of the male rats and concluded that the incidence of neoplasia among these animals was not evidence of a carcinogenic effect. Thus, both the testing laboratory and the consulting pathologist agreed that the increased incidence of bladder neoplasms in the high-dose male group was not significant. Nevertheless, there was a sizable difference between the total number of neoplasms (11) reported by the testing laboratory and the number (3) reported by the consulting pathologist.

Before arriving at a decision on the safety of FD&C Green No. 3, the agency requested the urinary bladder microslides from the petitioners, so that Bureau of Foods' pathologists could conduct their own blind review of the slides. The agency routinely examines slides from studies where concern has been raised that there may be treatment-related effects. The agency conducted the microscopic review to determine validity of the diagnoses of the urinary bladders of male rats presented by the petitioners' testing laboratory and by the petitioners' consulting pathologist; to evaluate further the apparent differences in the interpretation of urinary bladder lesions between the testing laboratory pathologist and the consulting pathologist; and to reach an independent determination on the significance of the urinary bladder lesions.

The agency pathologists found only three tumors, all in the high-dose group, in the urinary bladders of male rats in this study. They observed these tumors, which were transitional cell neoplasms, in the same three animals that the consulting pathologist had found neoplasms. Two of these neoplasms were diagnosed to be benign (papilloma) and one to be malignant (carcinoma). Furthermore, agency pathologists considered both the carcinoma and one of the papillomas to be borderline in morphology between neoplasia and hyperplasia and indicated that both of these lesions could have been given a non-neoplastic designation. The agency pathologists did not find any of the other transitional cell neoplasms that the performing laboratory had reported.

The petitioner's consultant pathologist not only disagreed with the testing laboratory on the number of neoplasms but also reported different incidences of transitional cell hyperplasia than the testing laboratory, including an apparent finding of an elevated incidence in the high dosage group. In a letter dated June 15, 1982 (item 184 in the administrative record), which he wrote with the testing laboratory's pathologist, the consultant pathologist said: "We feel there is indication of a weak proliferative effect on the bladder epithelium, but that there is insufficient progression of the lesions to regard the effect as clearly carcinogenic."

Agency pathologists have carefully examined all urinary bladder microslides for any evidence of a neoplastic process at this site associated with FD&C Green No. 3. They not only determined the incidence of transitional cell hyperplasia but also graded its severity. In contrast to the consulting pathologist, agency scientists found neither the incidence nor the severity of transitional cell hyperplasia to be associated with treatment. In addition, none of the areas of hyperplasia observed by the agency pathologists displayed any evidence of pre-neoplastic alteration. Thus, none of the pre-neoplastic indicators usually associated with carcinogenesis of the urinary bladder were found to be treatment-related.

Agency scientists have, therefore, concluded that the observation of only three neoplasms in the high-dose male group, two of which were of questionable neoplastic character, and the absence of support for a pre-neoplastic process in the observed hyperplasia, establish that there is no indication of a neoplastic effect on the urinary bladder from the administration of FD&C Green No. 3.[1]

Based upon the evaluation of the results of the two recently submitted chronic toxicity studies, the agency has determined that FD&C Green No. 3 is not carcinogenic to Charles River CD–1 mice or Charles River CD rats after lifetime dietary exposures of up to 5.0 percent. The agency has also completed its evaluation of other animal studies submitted by the petitioners for the purpose of establishing the safety of FD&C Green No. 3 for use in externally applied drugs and externally applied cosmetics. The data from these studies indicate that, with respect to dermal safety, FD&C Green No. 3 is nonirritating when applied daily to either intact or abraded skin. Furthermore, FD&C Green No. 3 was not found to be carcinogenic upon bi-weekly application to the skin of mice over their lifetimes. Therefore, FDA finds that it can conclude to a reasonable certainty that no harm will result from the petitioned uses of FD&C Green No. 3.

Using appropriate safety factors (see 21 CFR 70.40), the agency has also estimated a maximum acceptable daily intake of FD&C Green No. 3 for humans of approximately 2.5 milligrams per kilogram of body weight per day—150 milligrams per day for a 60 kilogram person. Based on its review of available data on the current uses of FD&C Green No. 3, FDA estimates that the upper limit of lifetime-average internal exposure to this color additive from food, including dietary supplements, drugs, and cosmetics is 4.2 milligrams per day (food, 1 milligram; drugs, 3 milligrams; and cosmetics, 0.2 milligram). Thus, the acceptable daily intake of FD&C Green No. 3 is approximately 37 times the estimated daily intake of the color additive.

During the safety review, the agency considered the possibility that derivatives of benzidine (benzidine is a known carcinogen) may occur in FD&C Green No. 3 as byproducts of the

[1] When the agency received the analyses of the testing laboratory and of the petitioners' consulting pathologist, FDA requested peer review by the National Toxicological Program (NTP) in anticipation that interpretation of the urinary bladder observations might be contentious. The agency did so before it had completed its own pathology slide review. NTP announced in the **Federal Register** of August 30, 1982, that it would conduct a peer review of FD&C Green No. 3 (47 FR 38209). On the basis of the agency's findings and conclusions concerning the color additive, however, FDA decided that peer review by NTP was not necessary (September 8, 1982; 47 FR 39616).

manufacture of the color additive. However, the presence of such contaminants can only be postulated. Upon careful consideration of this matter, the agency has determined that the postulated presence of benzidine derivatives of unestablished carcinogenic potential in FD&C Green No. 3 is too speculative to require the petitioners to undertake an investigation for their presence. The suitability of the color additive for permanent listing is appropriately established from the results of the animal studies wherein animals were challenged by very high doses of the color additive, and by the results of other studies submitted by the petitioners.

The agency is establishing new chemical specifications that identify the color additives more precisely than those specifications currently currently in 21 CFR Part 82. Also, the chemical name for the color additive in the new listing under 21 CFR Part 74 is different from the name currently listed under Part 82. The agency is listing the nomeclature designated in the Chemical Abstract Index Guide (September 1982) because the agency believes that it gives the best description of the color additive.

The agency concludes that it is necessary to include in the listing regulation for FD&C Green No. 3 a brief description of the manufacturing process to ensure the safety of the color additive. The agency is concerned that the color additive may contain potentially toxic impurities dependent upon the manufacturing process used to produce the color additive. The agency is not able at this time to set specifications that would control the presence of these impurities. The agency has contracted the National Academy of Sciences/National Research Council to develop appropriate specifications for color additives including FD&C Green No. 3 for use in food as part of the Food Chemicals Codex. These specifications will also be adopted for use in drugs and cosmetics. The agency concludes that specifying, through a general description, the manufacturing process in the regulations for these color additives will provide an adequate assurance of safety until suitable specifications can be developed. Production of the color additive by the specified method will assure qualitatively similar batches and thus adequately assure the absence of potentially toxic levels of impurities. The agency is including a description of the manufacturing procedure in 21 CFR 74.203(a) and is incorporating it by reference in 21 CFR 74.1203 and 74.2203.

## IV. Conclusion

The agency, following evaluation of the available data, concludes that FD&C Green No. 3 is safe for general use in food, and for internal and external use in drugs and cosmetics, except for use in the area of the eye, and that certification is necessary for the protection of the public health. The final toxicity study reports, interim reports, and the agency's toxicology evaluations of these studies are on file at the Dockets Management Branch (address above), and may be reviewed in that office between 9 a.m. and 4 p.m., Monday through Friday.

FDA notified the petitioners by letters dated May 14, 1976, August 15, 1977, and August 4, 1978, of the need for data to support the use of FD&C Green No. 3 in cosmetics intended for use in the area of the eye. In a letter dated October 24, 1978, FDA advised the petitioners to consider withdrawing their petition that sought approval of use of FD&C Green No. 3 in cosmetics intended for use in the area of the eye because it appeared that the required data from eye-area studies would not be readily available.

The petitioners have not submittted the data required to support eye-area use of this color additive. Therefore, that portion of the petition that was amended by the filing on March 5, 1976 (Docket No. 76C–0043) to include the permanent listing of FD&C Green No. 3 for eye-area use is not considered by the agency to be withdrawn without prejudice in accordance with the provisions of § 71.4 (21 CFR 71.4). Section 71.4 requires that such requested information be submitted within 180 days after filing of the petition, or the petition will be considered withdrawn without prejudice. Use of FD&C Green No. 3 in the area of the eye has never been covered by provisional listing. Future consideration by FDA of the permanent listing of FD&C Green No. 3 for eye-area use will require the submission of a new color additive petition for that use. The agency's listing of a color additive for general use in food, drugs, and cosmetics does not encompass eye-area use (see § 70.5 *General restrictions on color additives* (21 CFR 70.5)).

The agency has determined under 21 CFR 25.24(d)(5) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### Reference

The following information has been put on file at the Dockets Management Branch (address above) and is available for review in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. R. Peto, M. C. Pike, N. E. Day, R. C. Gray, P. N. Lee, S. Parish, J. Peto, S. Richards, and J. Wahrendorf, "Guidelines for Simple, Sensitive, Significance Tests for Carcinogenic Effects in Long-Term Animal Experiments," *in* "International Agency for Research on Cancer (IARC) Monographs on the Evaluation of the Carcinogenic risk of Chemicals to Humans," Supplement 2, IARC, Lyon, France, 1980, pp. 311–426.

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

Color additives, Cosmetics, Drugs, Foods.

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), Parts 74, 81, and 82 are amended as follows:

## PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By adding new § 74.203 to Subpart A, to read as follows:

### § 74.203 FD&C Green No. 3.

(a) *Identity.* (1) The color additive FD&C Green No. 3 is principally the inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl) methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353–45–9); with smaller amounts of the isomeric inner salt disodium salt of *N*-ethyl-*N*-[4-[[4-[ethyl[(3-sulfophenyl)methyl] amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide; *N*-ethyl-*N*-[4-[[4-[ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide and of *N*-ethyl-*N*-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two molecules from a mixture

consisting principally of 3-[(ethylphenylamino)methyl] benzensulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2'-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium 5-amino-2-formylbenzenesulfonate. This amine is diazotized and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) Color additive mixtures for food use (including dietary supplements) made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring food.

(b) *Specifications.* The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135° C (275° F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
Leuco base, not more than 5 percent.
Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.
Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.
2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.
Subsidiary colors, not more than 6 percent.
Chromium (as Cr), not more than 50 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring foods (including dietary supplements) generally in amounts consistent with current good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.1203 to Subpart B, to read as follows:

**§ 74.1203 FD&C Green No. 3.**

(a) *Identity and specifications.* (1) The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(2) Color additive mixtures for drug use made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in Part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring drugs generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

c. By adding new § 74.2203 to Subpart C, to read as follows:

**§ 74.2203 FD&C Green No. 3.**

(a) *Identity and specifications.* The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b).

(b) *Uses and restrictions.* The color additive FD&C Green No. 3 may be safely used for coloring cosmetics generally in amounts consistent with current good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of FD&C Green No. 3 shall be certified in accordance with regulations in Part 80 of this chapter.

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

2. Part 81 is amended:

**§ 81.1 [Amended]**

a. In § 81.1 *Provisional lists of color additives,* by removing the entry "FD&C Green No. 3" from the table in paragraph (a).

**§ 81.27 [Amended]**

b. In § 81.27 *Conditions of provisional listing,* by removing the entry "FD&C Green No. 3" from the table in paragraph (d).

## PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended by revising § 82.203, to read as follows:

**§ 82.203 FD&C Green No. 3.**

The color additive FD&C Green No. 3 shall conform in identity and specifications to the requirements of § 74.203(a)(1) and (b) of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before December 15, 1982, submit to the Dockets Management Branch (address above) written objection thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing and shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall become effective December 16, 1982, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the **Federal Register.**

(Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)); sec. 203, Pub. L. 86–618, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: November 15, 1982.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 82-31700 Filed 11-16-82; 8:45 am]

BILLING CODE 4160-01-M

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**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; Correction

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects the referenced final rule by adding report numbers that were omitted from a footnote in the preamble.

**FOR FURTHER INFORMATION CONTACT:** Agnes Black, Federal Register Writer (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 82-30081 at page 49628 in the **Federal Register** of November 2, 1982 (47 FR 49628), FDA issued a final rule that "permanently" listed D&C Green No. 5 for use in drugs and cosmetics, excluding use in the area of the eye. Footnote 1 in the preamble at page 49630 referred to certain NCI Technical reports. The report numbers were inadvertently omitted. Therefore, the footnote is corrected to read as follows:

[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 Nos. 103, 128, 145, 146, 156, 185, 123, and 163.

Dated: November 10, 1982.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 82-31505 Filed 11-18-82; 8:45 am]

BILLING CODE 4160-01-M

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**21 CFR Part 81**

**[Docket No. 76N-0366]**

## Provisional Listing of FD&C Green No. 3; 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 FD&C Green No. 3 for use as a color additive in foods, drugs, and cosmetics. A new closing date for FD&C Green No. 3 is being established to provide time for receipt and evaluation of any objections submitted in response to the final regulation (published elsewhere in this issue of the **Federal Register** approving the petition for the listing of FD&C Green No. 3 for these uses.

**DATES:** Effective November 15, 1982, the new closing date of FD&C Green No. 3 will be February 14, 1983.

**FOR FURTHER INFORMATION CONTACT:** Blondell Anderson, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5740.

**SUPPLEMENTARY INFORMATION:** The current closing date of November 16, 1982 for the provisional listing of FD&C Green No. 3 was established by notice published in the **Federal Register** of March 27, 1981 (46 FR 18958). FDA established the November 16, 1982, closing date for FD&C Green No. 3 to provide time for determining the applicability of the statutory standard for the listing of the color additive to the results of scientific investigations of FD&C Green No. 3.

After reviewing and evaluating the data, the agency has concluded that FD&C Green No. 3 is safe for its intended use. Therefore, elsewhere in this issue of the **Federal Register**, FDA is publishing a regulation that lists FD&C Green No. 3 for these uses. The regulations set forth below will postpone the November 16, 1982 closing date for the provisional listing of that color additive until February 14, 1983. This postponement will provide sufficient time for receipt and evaluation of comments or objections submitted in response to the listing regulation.

Because of the shortness of time until the November 16, 1982 closing date, FDA concludes that notice and public procedure on this regulation are impracticable. Moreover, good cause exists for issuing this postponement as a final rule because the agency has concluded that FD&C Green No. 3 is safe for its intended use under the Color Additive Amendments of 1960. This regulation will permit the uninterrupted use of this color additive until February 14, 1983. To prevent any interruption in the provisional listing of FD&C Green No. 3 and in accordance with 5 U.S.C. 553(d)(1) and (3), this regulation is being made effective on November 15, 1982.

### List of Subjects in 21 CFR Part 81

Color additives, Color additives provisional list, Cosmetics, Drugs.

Therefore, under 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), Part 81 is amended as follows:

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

**§ 81.1 [Amended]**

1. Section 81.1 *Provisional lists of color additives* is amended in paragraph (a) by changing the closing date for the entry "FD&C Green No. 3" in the table to read "February 14, 1983."

**§ 81.27 [Amended]**

2. Section 81.27 *Conditions of provisional listing* is amended in paragraph (d) by changing the closing date for the entry "FD&C Green No. 3" in the table to read "February 14, 1983."

*Effective date.* This final rule is effective November 15, 1982.

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

Dated: November 3, 1982.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 82-31699 Filed 11-16-82; 8:45 am]

BILLING CODE 4160-01-M

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**21 CFR Part 558**

## New Animal Drugs for Use in Animal Feeds; Lincomycin

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by the Upjohn Co. providing for use of a complete swine feed containing lincomycin for reduction in the severity of swine mycoplasmal pneumonia.

**EFFECTIVE DATE:** November 19, 1982.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-128), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4317.

**SUPPLEMENTARY INFORMATION:** The Upjohn Co., Kalamazoo, MI 49001, filed a supplemental NADA (97-505) providing for safe and effective use of a complete swine feed containing 200 grams of lincomycin per ton (g/ton) for reduction in the severity of mycoplasmal pneumonia caused by *Mycoplasma*

*hyopneumoniae*. The firm currently holds approval for use of the drug in complete feed at 40 and 100 g/ton for control and treatment of swine dysentery.

According to the Bureau of Veterinary Medicine's proposed supplemental new animal drug policy (42 FR 64367; December 23, 1977), this use of lincomycin at a level of 200 g/ton for reduction in the severity of swine mycoplasmal pneumonia requires a review of available residue information on the drug to assess the human risk from exposure to drug residues resulting from this new use at an increased dose, taking into account the proposed 6-day withdrawal period. Available microbiological tissue residue data indicate that a significant increase in human exposure to microbiologically active parent lincomyin residues is not anticipated with an increase in dosage level to 200 g/ton for 3 weeks provided that a 6-day withdrawal period is observed.

Standards prescribed in the agency's proposal of March 20, 1979 (44 FR 17070) on chemical compounds in food-producing animals were not applied to approval of this NADA. No evidence currently available indicates that lincomycin and its known or probable metabolites are teratogenic, mutagenic, or carcinogenic. The current approval is based on alternative criteria which assure that the product is safe and on factors which justify the equitable treatment of this sponsor who adequately completed drug development testing according to scientific standards existing before March 20, 1979.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine 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 Bureau's finding of no significant impact and the evidence supporting this finding, contained in an environmental impact analysis report (pursuant to 21 CFR 25.1(j)) may be seen in the Dockets Management Branch (address above).

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

**List of Subjects in 21 CFR Part 558**

Animal drugs; Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.325 is amended by adding new paragraph (f)(2)(iv) to read as follows:

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

**§ 558.325 Lincomycin.**

* * * * *

(f) * * *

(2) * * *

(iv) *Amount per ton.* 200 grams.

*(a) Indications for use.* For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*.

*(b) Limitations.* Feed as sole ration for 21 days; not to be fed to swine that weigh more than 250 pounds; withdraw 6 days before slaughter.

* * * * *

*Effective date.* November 19, 1982.

(Sec.512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: November 15, 1982.

**Gerald B. Guest,**

*Acting Director, Bureau of Veterinary Medicine.*

[FR Doc. 82-31756 Filed 11-18-82; 8:45 am]

BILLING CODE 4160-01-M

## COPYRIGHT ROYALTY TRIBUNAL

**37 CFR Part 308**

**[Docket No. CRT 81-2]**

## Adjustment of the Royalty Rate for Cable Systems; Federal Communications Commission's Deregulation of the Cable Industry

**AGENCY:** Copyright Royalty Tribunal.

**ACTION:** Final rule.

**SUMMARY:** The Copyright Royalty Tribunal amends its rule establishing the rate of royalty payments for the secondary transmission to the public by a cable system of a primary transmission made by a broadcast station, to establish the schedule of royalty fees for the additional broadcasting signals and programs carried by cable systems as a result of the repeal by the Federal Communications Commission of its rules restricting the carriage of distant signals and providing for syndicated program exclusivity.

**DATE:** Effective December 20, 1982.

**FOR FURTHER INFORMATION CONTACT:** Commissioner Thomas C. Brennan, Copyright Royalty Tribunal, 1111 20th Street, NW, Room 450, Washington, DC 20036, (202) 653–5175.

**SUPPLEMENTARY INFORMATION:**

**Background and Chronology**

In July of 1980, the Federal Communications Commission (FCC) repealed the distant signal carriage and program syndication exclusivity restrictions on cable transmissions *(Report and Order in Docket Nos. 20988 and 21284*, 79 F.C.C. 2d 663 (1980)). However, the FCC's order was stayed by a Federal court pending an appeal of that decision. On June 16, 1981, the FCC's order won judicial approval. *Malrite T.V. of New York, Inc.*, v. *FCC*, 652 F.2d 1140 (2d Cir. 1981), and the stay was vacated on June 25, 1981.

On August 11, 1981, the National Cable Television Association (NCTA) filed a "Petition to Waive Rule 301.63 and To Initiate Cable Television Copyright Royalty Fee Adjustment Proceedings" on behalf of the cable operators with the Copyright Royalty Tribunal (Tribunal). In the Federal Register of August 18, 1981 (46 FR 41840), the Tribunal directed interested parties to submit comments on the issues presented in the NCTA petition and whether NCTA is a user of copyrighted works "with a significant interest in the royalty rate in which an adjustment is requested" no later than September 24, 1981.

The American Society of Composers, Authors and Publishers (ASCAP) filed a "Petition to Commence Proceedings" to adjust the cable compulsory license fee with the Tribunal on September 24, 1981.

Pursuant to the Tribunal's notice, comments on the NCTA petition were filed by September 24, 1981 by the Motion Picture Association of America (MPAA); National Association of Broadcasters (NAB); ASCAP; Major League Baseball, National Basketball Association, National Collegiate Athletic Association, National Hockey League, and North American Soccer League (Joint Sports Claimants); Broadcast Music, Inc. (BMI); and NCTA. MPAA filed their comments on the NCTA petition with the Tribunal on September 14, 1981, and in addition requested the Tribunal to adopt certain interim cable television rates and to make a ruling as to the effective date of