

redeemed soybeans would collect and remit the assessment or the producer would remit the assessment if the producer markets the redeemed soybeans as processed soybeans or soybean products of that producer's own production.

Accordingly, § 1220.223 Assessments is amended to reflect these changes. Also, the definitions of first purchaser in § 1220.110 and of net market price in § 1220.115 are amended.

Pursuant to 5 U.S.C. 535, it is found and determined, upon good cause, that it is impracticable, unnecessary and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register*. The Soybean Promotion and Research Order was published as a final rule in the July 9, 1991, issue of the *Federal Register* (56 FR 31043). The Order was made effective on July 9, 1991, except that § 1220.223 concerning assessments is effective on September 1, 1991. This action amends § 1220.223 and therefore, the revisions made herein should be made effective on the same date as that section of the Orders.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Soybeans and soybean products, Reporting and Recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1220 is amended as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

1. The authority citation for 7 CFR part 1220 continues to read as follows:

Authority: Title XIX, Pub. L. No. 101-624, 104 Stat. 3359, 3881 (7 U.S.C. 6301-6311).

2. Section 1220.110 is amended by revising paragraph (b) to read as follows:

§ 1220.110 First purchaser.

(b) In any case in which soybeans are pledged as collateral for a loan issued under any federal price support loan program and the soybeans are forfeited by the producer in lieu of loan repayment, the Commodity Credit Corporation.

3. Section 1220.115 is amended by revising paragraph (b) to read as follows:

§ 1220.115 Net market price.

(b) For soybeans pledged as collateral for a loan issued under any price support loan program, administered by the Commodity Credit Corporation, where the soybeans are forfeited by the producer in lieu of loan repayment, the principal amount of the loan.

4. Section 1220.223 is amended by revising the first sentence of paragraph (a)(1) and (a)(5)(ii) to read as follows:

§ 1220.223 Assessments.

(a)(1) Except as prescribed by regulations approved by the Secretary or as otherwise provided in this section, each first purchaser of soybeans shall collect an assessment from the producer, and each producer shall pay such assessment to the first purchaser, at the rate of one-half of one percent (0.5%) of the net market price of the soybeans purchased. * * *

(5) * * *

(ii)(A) If a producer pledges soybeans grown by that producer as collateral for a loan issued by the Commodity Credit Corporation and if that producer forfeits said soybeans in lieu of loan repayment, the Commodity Credit Corporation shall at the time of the loan settlement, bill the producer for the assessments due based on 0.5 percent of the principal loan amount received by the producer, and notify the producer to remit the amount of assessment specified in the bill to the Qualified State Soybean Board in the State in which the soybeans were pledged, or if no Qualified State Soybean Board exists in such State, the Board. The Commodity Credit Corporation will also notify the Qualified State Soybean Board in the State in which the soybeans were pledged, or if no Qualified State Soybean Board exists in such State, the Board, of its acquisition of the forfeited soybeans and the amount of assessments due as a result of the loan settlement. The producer shall be responsible for remitting the assessment as of the date of the settlement of the loan and billing of the assessment by the Commodity Credit Corporation as prescribed in regulations approved by the Secretary.

(B) If a producer markets soybeans which have been pledged as collateral for a loan issued by the Commodity Credit Corporation, the first purchaser shall collect and remit the assessments due pursuant to paragraph (a)(1) of this section, or if a producer markets such soybeans as processed or as soybean products the producer shall remit the

assessment pursuant to paragraph (a)(2) of this section.

Done at Washington, DC, August 27, 1991
John E. Frydenlund,
Acting Assistant Secretary, Marketing and
Inspection Services.

[FR Doc. 91-20938 Filed 8-29-91; 8:45 am]

BILLING CODE 3410-02-M

7 CFR Part 1220

[No. LS-91-005]

Soybean Promotion and Research; Rules and Regulations

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule implements the Soybean Promotion and Research Order, which established a national and industry-funded soybean promotion and research program. This rule includes provisions (1) detailing the collection and remittance process; (2) establishing a form of certification for exempt transactions; (3) identifying the Qualified State Soybean Boards; (4) providing refund procedures; and (5) establishing procedures for remitting assessments due on forfeited soybeans pledged as collateral for Commodity Credit Corporation loans.

DATES: This interim final rule is effective September 1, 1991. Comments on the interim rule must be received by September 30, 1991.

ADDRESSES: Send two copies of comments to the Marketing Programs Branch; Livestock and Seed Division; Agricultural Marketing Service, U.S. Department of Agriculture, room 2624-S; P.O. Box 96456; Washington, DC 20090-6456, where they will be available for public inspection during regular business hours. Comments concerning the information collection requirements contained in this action should also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Attention: Desk Officer for Agricultural Marketing Service, USDA.

FOR FURTHER INFORMATION CONTACT: Ralph L. Tapp, Chief; Marketing Programs Branch; Livestock and Seed Division; AMS, USDA, room 2624-S; P.O. Box 96456; Washington, DC 20090-6456. (Telephone: 202/382-1115).

SUPPLEMENTARY INFORMATION: Prior document: Final Rule—Soybean Promotion and Research Order (published July 9, 1991) (56 FR 31043).

Regulatory Impact

This interim final rule was reviewed in accordance with Executive Order No. 12291 and Departmental Regulation No. 1512-1 and has been classified as a "nonmajor" rule because it does not meet the criteria for a major rule as stated in the Order.

This action was also reviewed under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This rule includes provisions: (1) Detailing the collection and remittance process; (2) establishing a form of certification of exempt transactions (3) identifying the Qualified State Soybean Boards; (4) providing refund procedures; and (5) establishing procedures for remitting assessments due on forfeited soybeans pledged as collateral for a Commodity Credit Corporation loan.

The most recent available census of agricultural producers indicates that there are 439,093 soybean producers in the United States, an estimated 431,710 of whom would be classified as small businesses under the criteria established by the Small Business Administration (13 CFR § 121.2). Soybean producers are required to pay an assessment of one-half of one percent of market value of soybeans marketed. In addition an estimated 10,000 first purchasers of soybeans are required to collect and remit the assessments. Although the assessments are expected to total approximately \$50-\$60 million dollars annually, the economic impact of a one-half of one-percent of market value assessment on each individual producer, including small producers, will not be significant. Reporting and recordkeeping requirements are imposed on first purchasers of soybeans and on producers marketing soybeans and on producers marketing soybeans and soybean products of their own production. This burden should average less than 5 hours per year, so its economic impact will not be significant. In addition, the promotion and research program funded by the assessments is expected to benefit the producers and first purchasers by expanding and maintaining new and existing domestic and foreign markets and uses for soybeans and soybean products. Therefore, the Administrator of the Agricultural Marketing Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) the reporting and recordkeeping requirements included in part 1220 were

previously approved by the Office of Management and Budget (OMB) and were assigned OMB No. 0581-0093, except that OMB No. 0581-0001 was assigned to an information collection requirement in § 1220.525(a)(2). There are an estimated 439,093 soybean producers and an estimated 10,000 first purchasers. Information collection requirements contained in this action include a report by persons marketing soybeans, processed soybeans, or soybean products and persons collecting assessments on soybeans (an estimated 10,000 respondents with an estimated average reporting burden of one hour per response); a certification form to claim non-producer status (an estimated 2,000 respondents with an estimated average reporting burden of 0.03 hours per response); and an application for a refund of assessments (an estimated 30,000 respondents with an estimated average reporting burden of 0.08 hours per response). Comments concerning the information collection requirements contained in this action, should also be sent to the Office of Information and Regulatory Affairs; Office of Management and Budget; Washington, DC 20503. Attention: Desk Officer for Agricultural Marketing Service, USDA.

Background

The Soybean Promotion, Research, and Consumer Information Act (Act) approved November 28, 1990, as subtitle E of title XIX of the Food, Agriculture, Conservation, and Trade Act of 1990 provides for the establishment of a national program of promotion, research, consumer information, and industry information designed to strengthen the soybean industry's position in the marketplace, to maintain and expand existing domestic and foreign markets and uses for soybeans and soybean products and to develop new markets and uses for soybeans and soybean products. This program will be financed by assessments on soybeans. Pursuant to the Act, a Soybean Promotion and Research Order has been issued and assessments will begin September 1, 1991. The Order requires that first purchasers of soybeans shall collect an assessment from producers and remit such assessments to the Qualified State Soybean Board in the first purchaser's State or to the Board.

This rule includes provisions: (1) Detailing the collection and remittance process; (2) establishing a form of certification for exempt transactions; (3) identifying the Qualified State Soybean Boards; (4) providing refund procedures; and (5) establishing procedures for remitting assessments on forfeited

soybeans pledged as collateral on Commodity Credit Corporation loans.

The Soybean Promotion, Research, and Consumer Information Act authorizes the establishment of a national soybean promotion, research, consumer information, and industry information program. The program will be funded by an assessment of 0.5 of one percent of the net market price of soybeans marketed by soybean producers.

The final Order establishing a soybean promotion and research program was published in the July 9, 1991, issue of the *Federal Register* (56 FR 31043). The Order requires that the first purchaser remit assessments to the Qualified State Soybean Board or to the Board if the State does not have a Qualified State Soybean Board. The Order further provides that producers participating in such Qualified State Soybean Promotion and Research programs shall be entitled to a credit of up to 0.25 of one percent of the net market value of soybeans marketed for participating in such a program. The remaining portion of the assessment will be forwarded to the Board to fund national promotion and other authorized activities while the portion credited to the Qualified State Soybean Boards will be used for comparable programs at the State level.

The program is administered by a United Soybean Board composed of soybean producers appointed by the Secretary from nominations submitted by industry organizations. The Board held its initial meeting on July 21 and 22, 1991.

The Board has reviewed 29 applications from State soybean promotion entities pursuant to § 1220.228 of the Order. These Qualified State Soybean Boards are listed in § 1220.312 of these rules and regulations. The address of the Board and the addresses of the Qualified State Soybean Boards will be as published in a separate notice which will be updated from time to time as necessary. The addresses of Qualified State Soybean Boards may be obtained from the Board. First purchasers or producers responsible for remitting assessments in the 21 States which do not have Qualified State Soybean Boards are required by the Order to remit the assessments collected to the Board.

During its meeting on July 21-22, 1991, the Board recommended the adoption of rules and regulations to implement the collection of assessments pursuant to the Order.

The Board sought to clarify the collection of assessments in the

marketing situation involving deliveries on futures contracts. In these transactions there could be confusion as to the person responsible for remitting assessments. The Board has determined that the collection and remittance process would be most effective and efficient if the producer is responsible for remitting the assessment.

In addition, these rules and regulations further specify responsibilities relating to assessments for purchases on a contract basis and for soybeans purchased for seedstock. Section 1220.223(a)(2) of the Order specifies that "any producer marketing processed soybeans or soybean products of that person's own production shall remit to a Qualified State Soybean Board or to the Board an assessment on such soybeans or soybean products at a rate of one-half of one percent (0.5%) of the net market price of the soybeans involved or the equivalent thereof." The Order did not specify when this assessment obligation would be incurred. It was the intent of the Order that the assessment on such soybeans would be incurred at the time of sale of the processed soybeans or soybean products. The assessment on soybeans forfeited in lieu of repayment of a Commodity Credit Corporation loan shall attach at the time of loan settlement and billing of such assessments by Commodity Credit Corporation.

These regulations provide procedures for certification of non-producer status for subsequent sales of soybeans.

Producers may obtain refunds of assessments paid prior to the date the results of the continuance referendum as contemplated by the Act are announced. These rules and regulations contain procedures relating to this refund period. Also, a provision concerning the OMB control number is added to subpart B.

Pursuant to 5 U.S.C. 553 it is found and determined, upon good cause, that it is impractical, unnecessary and contrary to the public interest to give preliminary notice prior to putting the rule into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication of this rule in the *Federal Register*. The Soybean Promotion and Research Order was published as a final rule in the July 9, 1991, issue of the *Federal Register* (56 FR 31043). The Order was made effective on July 9, 1991, except that § 1220.223 concerning assessments is effective on September 1, 1991. This action includes provisions: (1) Establishing a form of certification for exempt transactions; (2) detailing the collection and remittance process; (3) identifying the Qualified State Soybean

Boards; (4) providing refund procedures; and (5) establishing procedures for remitting assessment on forfeited soybeans which had been pledged as collateral on Commodity Credit Corporation loans. Therefore, the provisions made herein should be made effective on the same date as the assessment provisions of the Order.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Soybeans and soybean products, Reporting and recordkeeping requirements.

Title 7 of the CFR, part 1220 is amended as follows:

PART 1220—SOYBEAN PROMOTION AND RESEARCH

1. The authority citation for part 1220 continues to read as follows:

Authority: Title XIX, Pub. L. No. 101-624, 104 Stat. 3359, 3881 (7 U.S.C. 6301-6311).

2. Subpart B is added to read as follows:

Subpart B—Rules and Regulations

Definitions

Sec.
1220.301 Terms Defined.

Assessments

- 1220.310 Assessments.
- 1220.311 Collection and Remittance of Assessments.
- 1220.312 Remittance of Assessments and Submission of Reports to United Soybean Board or Qualified State Soybean Board.
- 1220.313 Qualified State Soybean Boards.
- 1220.314 Document Evidencing Payment of Assessments.
- 1220.315 Certification of Non-Producer Status for Certain Transactions.

Refund of Assessments

- 1220.330 Producer Refund of Assessments.
- 1220.331 Procedure for Obtaining a Refund.
- 1220.332 OMB Control Numbers.

Subpart B—Rules and Regulations

§ 1220.301 Terms defined.

As used throughout this subpart, unless the context otherwise requires, terms shall have the same meaning as the definition of such terms as appears in subpart A of this part.

§ 1220.310 Assessments.

(a) A 0.5 percent of the net market price per bushel assessment on soybeans marketed shall be paid by the producer of the soybeans in the manner designated in § 1220.311.

(b) If more than one producer shares the proceeds received for the soybeans

marketed, each such producer is obligated to pay that portion of the assessments which is equivalent to each producer's proportionate share of the proceeds.

(c) Failure of the first purchaser to collect the assessment on each bushel of soybeans marketed as designated in § 1220.311 shall not relieve the producer of the producer's obligation to pay the assessment to the appropriate Qualified State Soybean Board or the United Soybean Board as required in § 1220.312.

§ 1220.311 Collection and remittance of assessments.

(a) Except as otherwise provided in this section, each first purchaser making payment to a producer for soybeans marketed by a producer shall collect from that producer at the time of settlement of that producer's account an assessment at the rate of 0.5 percent of the net market price per bushel of soybeans marketed and shall be responsible for remitting the assessment to the Qualified State Soybean Board or the United Soybean Board as provided in § 1220.312. The first purchaser shall give to the producer a receipt indicating payment of the assessment.

(b) A first purchaser who purchases soybeans pursuant to a contract with a producer, either on a volume basis or on a per acre basis, shall be responsible for remitting the assessment due on soybeans purchased as required in § 1220.312. Such assessment shall be based upon 0.5 percent of the net market price specified in the contract and shall be collected from the producer at the time of final settlement.

(c) A first purchaser who purchases soybeans pursuant to a contract or otherwise, with the intent of utilizing such soybeans for seed stock shall be responsible for remitting the assessment due on such soybeans as required in § 1220.312. Such assessment shall be collected from the producer at the time of final settlement for such soybeans. The assessment on soybeans marketed for use as seed stock shall be based upon 0.5 percent of the posted county price for soybeans on the day of settlement as posted at the local ASCS office for the county in which the first purchaser is located.

(d) Any producer marketing processed soybeans or soybean products of that producer's own production either directly or through retail or wholesale outlets shall be responsible for remitting to the Qualified State Soybean Board or the United Soybean Board pursuant to § 1220.312, an assessment on the number of bushels of soybeans processed or manufactured into soybean products at

the rate 0.5 percent of the net market price of the soybeans involved or the equivalent thereof. The assessment shall attach upon date of sale of the processed soybeans or soybean products and shall be based upon the posted county price for soybeans on the date of the sale as posted at the local ASCS office for the county in which the producer is located. The producer shall remit the assessment in the manner provided in § 1220.312.

(e) Any producer contracting to market processed soybeans or soybean products of that producer's own production shall be responsible for remitting to the Qualified State Soybean Board or the United Soybean Board pursuant to § 1220.312, an assessment on the number of bushels of soybeans processed or manufactured into soybean products at the rate of 0.5 percent of the net market price of the soybeans involved or the equivalent thereof. The assessment shall attach upon the date of final settlement of the contract for such processed soybeans or soybean products and shall be based upon the posted county price for soybeans on the date of final settlement as posted at the local ASCS office for the county in which the producer is located. The producer shall remit the assessment in the manner provided in § 1220.312.

(f) A producer delivering soybeans of the producer's own production against a soybean futures contract shall be responsible for remitting an assessment at the rate of 0.5 percent of net market price as specified in settlement documents. The assessment shall attach at the time of delivery and the producer shall remit the assessment due in accordance with § 1220.312.

(g) A producer who forfeits soybeans of that producer's own production which were pledged as collateral on a loan issued by CCC shall remit an assessment at the rate of 0.5 percent of the net market price of such soybeans. The assessment shall attach upon the date of the settlement statement prepared and issued to the producer by the CCC and shall be based upon the principal amount of the loan for the soybeans as specified by CCC in the settlement statement. The Commodity Credit Corporation shall bill the producer for the assessments due. The producer shall remit the assessment due in accordance with § 1220.312.

§ 1220.312 Remittance of assessments and submission of reports to United Soybean Board or Qualified State Soybean Board.

(a) Each first purchaser and each producer responsible for the remittance of assessments shall remit assessments

and submit a report of assessments to the Qualified State Soybean Board in the State in which each first purchaser or each producer responsible for the remittance of assessments is located or if there is no Qualified State Soybean Board in such State, then to the United Soybean Board as follows:

(b) First purchasers and producers responsible for remitting assessments shall remit assessments and reports on a monthly or quarterly basis depending on the State or region in which the first purchasers or producers are located. The reporting period for each State and region shall be as follows:

Monthly	Quarterly
Arkansas	Alabama
Delaware	Florida
Iowa	Georgia
Kansas	Illinois
Kentucky	Indiana
Louisiana	Maryland
Michigan	North Dakota
Minnesota	Nebraska
Missouri	New Jersey
Mississippi	Ohio
North Carolina	Oklahoma
South Carolina	Pennsylvania
Tennessee	South Dakota
Texas	
Virginia	
Wisconsin	
Eastern Region	
Western Region	

(c) *Reports.* Each first purchaser or producer responsible for remitting assessments shall make reports on forms made available by the United Soybean Board or on Qualified State Soybean Board forms which contain the information required in § 1220.241 and are approved by the Board. A first purchaser with multiple facilities or purchasing locations within a State shall have the option to submit a single, consolidated report specifying the combined volume of soybeans purchased from the producers in the State. Reports shall be submitted with assessments due in accordance with the provisions of paragraph (d).

(d) *Remittances.* Each first purchaser or producer responsible for remitting assessments shall remit all assessments to the Qualified State Soybean Board, its designee, or the United Soybean Board. All assessments shall be remitted in the form of a check or money order payable to the order of the applicable Qualified State Soybean Board or the United Soybean Board and shall be sent to the designated address not later than the 15th day of the month following the month or quarter in which the soybeans, processed soybeans, or soybean products were marketed and shall be accompanied by the reports required by paragraph (c). All remittances shall be received subject to collection and payment at par.

(e) *Receipt of Reports and Remittances.* The timeliness of receipt

of reports and assessments by the Board or Qualified State Soybean Board shall be based on the applicable post mark date or the date actually received by the Board or the Qualified State Soybean Board whichever is earlier.

§ 1220.313 Qualified State Soybean Boards.

The following State Soybean promotion organizations shall be Qualified State Soybean Boards. First purchasers and producers responsible for remitting assessments located in States which have a Qualified State Soybean Board shall remit assessments accompanied by the required reports to the Qualified State Soybean Board in the State in which the first purchaser or producer responsible for remitting assessments is located.

Alabama Soybean Producers Board
 Arkansas Soybean Promotion Board
 Delaware Soybean Board
 Florida Soybean Advisory Council
 Georgia Agricultural Commodity Commission for Soybeans
 Illinois Soybean Program Operating Board
 Iowa Soybean Promotion Board
 Indiana Soybean Development Council, Inc.
 Kansas Soybean Commission
 Kentucky Soybean Promotion Board
 Louisiana Soybean Promotion Board
 Maryland Soybean Board
 Soybean Promotion Committee of Michigan
 Minnesota Soybean Research and Promotion Council
 Mississippi Soybean Promotion Board
 Missouri Soybean Merchandising Council
 Nebraska Soybean Development, Utilization, and Marketing Board
 New Jersey Soybean Board
 North Carolina Soybean Producers Association
 North Dakota Soybean Council
 Ohio Soybean Council Board of Trustees
 Oklahoma Soybean Commission
 Pennsylvania Soybean Board
 South Carolina Soybean Board
 South Dakota Soybean Research and Promotion Council
 Tennessee Soybean Promotion Board
 Texas Soybean Producers Board
 Virginia Soybean Board
 Wisconsin Soybean Marketing Board, Inc.

§ 1220.314 Document evidencing payment of assessments.

(a) Each first purchaser responsible for remitting an assessment to a Qualified State Soybean Board or the United Soybean Board, is required to give to the producer from whom the first purchaser collected an assessment written evidence of payment of the assessment containing the following information:

- (1) Name and address of the first purchaser.
- (2) Name of producer who paid assessment.

- (3) Number of bushels sold.
- (4) Net Market price.
- (5) Total assessments paid by the producer.
- (6) Date.
- (7) State in which soybeans were grown.
- (b) [Reserved].

§ 1220.315 Certification of non-producer status for certain transactions.

(a) A person marketing soybeans, processed soybeans, or soybean products on which an assessment has been collected may claim non-producer status and shall not be required to pay an assessment if such person certifies to the purchaser that the assessment has been collected and remitted or will be remitted in a timely fashion.

(b) Each person claiming non-producer status pursuant to this subpart shall provide purchasers with a Statement of Certification of Non-Producer Status on a form approved by the Board and the Secretary. A Statement of Certification of Non-Producer Status form shall be required for each transaction except that one such form, if approved by the Board, may be used to cover all transactions during a specified period not to exceed 12 consecutive months. The Board is authorized to approve a stamp process for providing such certification on invoices or other methods of such certification upon individual written requests. Forms and information on requirements for stamps and other methods of certification can be obtained from the Board.

(c) A copy of the Statement of Certification of Non-Producer Status shall be forwarded, upon request, by the subsequent purchasers to the Qualified State Soybean Board or the Board.

§ 1220.330 Producer refund of assessments.

(a) Assessments Paid Prior to Continuance Referendum

(1) Any producer from whom an assessment is collected prior to the date the continuance referendum results are announced and remitted to a Qualified State Soybean Board or the United Soybean Board, or who pays an assessment to a Qualified State Soybean Board or to the United Soybean Board, and who is not in favor of supporting the promotion and research program as provided for in this Part shall have the right to demand and receive from the Qualified State Soybean Board to which the assessment was paid subject to paragraph (a)(2) of this section, or the Board, a refund of such assessment upon submission of proof satisfactory to the Qualified State

Soybean Board or Board that the producer paid the assessment for which a refund is sought.

(2) Contributions by a producer to a Qualified State Soybean Board for which the producer has received credit pursuant to § 1220.223(a)(3) of this Part shall not be refunded by a Qualified State Soybean Board unless:

(i) The Qualified State Soybean Board is authorized or required to pay refunds; and

(ii) the producer has requested a refund from the Qualified State Soybean Board in compliance with the State's procedure for refunds.

(3) Producers shall submit refund requests to the Qualified State Soybean Board in the State in which the soybeans were grown. If there is not a Qualified State Soybean Board operating in such State, the producer shall submit refund requests to the United Soybean Board.

(b) Assessments Paid After the Conduct of the Continuance Referendum
[Reserved].

§ 1220.331 Procedure for obtaining a refund.

(a) Any producer requesting a refund shall mail an application on the prescribed form to the Qualified State Soybean Board in the State in which the soybeans were grown or if there is no Qualified State Soybean Board in the State, to the Board within ninety days (90) from the date the assessments were due from such producer.

(b) In order to receive a refund pursuant to this subpart, a producer must attach to the refund application a copy of the document evidencing payment provided by the first purchaser to the producer as required by § 1220.314. Such refund request must be submitted pursuant to § 1220.224 and § 1220.225 of this part.

(c) In those States in which a Qualified State Soybean Board operates and is required to pay refunds pursuant to State law such refunds will be paid pursuant to such State law. In those States in which refunds are not required by State law, refund requests shall be paid by the Qualified State Soybean Board or the United Soybean Board within sixty days (60) of receipt of the refund request by the Qualified State Soybean Board or the United Soybean Board. Refunds shall be paid in a manner consistent with § 1220.224 of this part.

§ 1220.332 OMB control numbers.

The control number assigned to the information collection requirements by the Office of Management and Budget (OMB) pursuant to the Paperwork

Reduction Act of 1980, Public Law 96-511, is OMB number 0581-0093, except that OMB No. 0581-0001 was assigned to an information collection requirement in § 1220.525(a)(2).

Done at Washington, DC.

John E. Frydenlund,
Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 91-20935 Filed 8-29-91; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket Nos. 80N-0428 and 82N-0342]

Colorants for Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food additive regulations to list those food additives that may be safely used as colorants in polymers that contact food. The agency is responding to five food additive petitions and is transferring the listings of a number of other colorants from the regulations that provide for their use to a single regulation on colorants in polymers. FDA is also providing for additional uses of phthalocyanine green and quinacridone red, for the use of D&C Red No. 7 and its lakes, and for the use of additional shades of phthalocyanine blue in food-contact polymers.

DATES: Effective August 30, 1991; written objections and requests for a hearing by September 30, 1991.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. History of Rulemaking

FDA initiated a comprehensive rulemaking on colorants used in food-contact polymers with a proposal entitled "Colorants for Plastics," which it published in the *Federal Register* of June 6, 1972 (37 FR 11255). The 1972

proposal announced five food additive petitions that the agency received requesting issuance of food additive regulations for a number of colorants for use in polymers. These five petitions were submitted to FDA following expiration of the 1965 interim provisions providing for the use of various colorants (21 CFR 121.91 removed by 31 FR 8008, June 7, 1966).

On October 14, 1983, FDA issued a final rule (48 FR 46773) based on aspects of the June 6, 1972 proposal. In this final rule, the agency defined the term "colorant" as it pertains to food additives used in food-contact polymers. It also established a new section in the food additive regulations, § 178.3297 Colorants for polymers (21 CFR 178.3297), to provide a single regulation for the listing of all food additives that can be used as colorants in food-contact polymers. However, the agency did not respond to the five food additive petitions announced in the 1972 proposal. FDA stated that it would do so in a future issue of the Federal Register. However, the agency solicited comments on the October 14, 1983 final rule, because of the amount of time that had passed since the June 6, 1972 proposal.

In the Federal Register of April 6, 1988 (53 FR 11402), FDA issued a tentative final rule that responded to objections to the 1983 final rule, as well as to the five food additive petitions announced in the 1972 proposal. The agency proposed to list in § 178.3297 those food additives that were the subjects of the petitions and that had been shown to be safe for use as colorants for polymers that contact food. The agency also proposed to transfer to § 178.3297 the listings of all other colorants for food-contact polymers. As stated in the tentative final rule, regulations for the food additive use of colorants in polymers had been scattered throughout parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178).

FDA also requested data on the environmental impact of expanded use of certain colorants and on the use in food-contact polymers of the color additives and their lakes that are listed for use in ingested drug and cosmetics. The agency stated that it could not consider regulating these substances for use in polymers without the environmental data.

This final rule is intended to address the issues raised in these rulemakings.

II. Comments on the April 6, 1988 Tentative Final Rule

The agency provided 60 days for comment on the tentative final rule. It received five requests from industry

representatives for an extension of the comment period, which it granted, extending the comment period to August 5, 1988, in a notice published in the Federal Register of June 3, 1988 (53 FR 20335).

FDA received 13 comments from industry and from the trade associations that represent the plastics industry and the carbon black industry. Seven of these comments supplied environmental data for new uses of colorants in polymers. These environmental comments and a comment on the economic impact of the proposed action are discussed in sections III and IV of this document. The other issues raised in the comments, and the agency's responses to them, are set forth below:

1. Comments from a chemical company and a trade association raised several arguments regarding whether colorants should be considered to be food additives. The comments contended that the information that FDA cited in the tentative final rule, Fick's Laws of Diffusion and data from a number of petitions, is insufficient to support the conclusion that colorants used in food-contact polymers may reasonably be expected to migrate to food in more than insignificant amounts.

The comments stated that this information does not meet the intent of the court decision in *Monsanto Co. v. Kennedy*, 613 F.2d 947, 955 (1979), that the determination that a substance migrates to food, and thus is a good additive, be based upon a "meaningful projection from reliable data." The comments argued that under *Monsanto Co. v. Kennedy*, a substance must migrate to food "in more than insignificant amounts" to be a food additive.

The trade association comment submitted three letters that had been issued by FDA in which the agency had concluded that a particular use of a colorant was "not a food additive situation" when used in a food-contact polymer. The comment asserted that these letters refute the statement in the tentative final rule that "colorants will migrate to food from all polymers," and that they make clear that FDA recognizes that Fick's Laws are not applicable at low concentrations.

The comments requested that FDA reverse its conclusion that colorants used in food-contact polymers are reasonably expected to migrate to food and conclude that they are not food additives based upon the agency's further consideration of these issues. The comments also asked the agency to acknowledge that companies may determine for themselves that colorants do not migrate to food at significant

levels and therefore are not food additives.

Although FDA believes that the tentative final rule fully addressed most of the issues raised by these comments, the agency recognizes that there is confusion about the circumstances in which it will require a food additive regulation and those that it considers to be "not a food additive situation." Therefore, the agency will clarify its position in response to these comments.

In the tentative final rule, published on April 6, 1988, the agency stated, "Existing theory and data produced by industry demonstrate that, under normal conditions of use, colorants will migrate to food from all polymers." The agency was saying in this statement that based on data on the use of colorants in polymers that it has reviewed (e.g., see food additive petitions OR2534, 7B4024, 7B4033, 8B4079, and 9B4158), FDA has concluded that a meaningful projection can be made that all colorants in polymers will migrate at some level to the foods with which the polymers come into contact. Thus, an appropriate factual basis does exist to find that all colorants used in polymers are food additives.

The agency has, however, issued letters in which it has stated that, given the specific circumstances presented, it would not require food additive petitions for particular colorants that were to be used in food-contact polymers. The agency statements in those letters were not intended to imply that the colorant did not meet the definition of a food additive. Rather, in issuing those letters, the agency was exercising its discretion, which the court cited in *Monsanto Co. v. Kennedy*, to make case-by-case determinations as to whether the level of migration in a particular situation is such as not to be of regulatory concern. The agency findings of "no objection" or "not a food additive situation" in those letters are not inconsistent with the position taken by the agency in this document that colorants are food additives. What the agency meant by those findings was that based on the data submitted, and under the specific conditions of use of the colorants described in those opinions, the agency could conclude that the colorants would migrate to food and thus meet the literal definition of food additives, but that the colorants would migrate at such low levels as to not be of regulatory concern as food additives.

Therefore, after considering the comments, the agency concludes that there is no factual basis upon which to alter its finding that, under normal conditions of use, colorants (1) have

been shown to migrate to food from polymers, (2) are food additives, and (3) are subject to section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348).

Finally, the agency cannot do as one comment would have it do and acknowledge that companies may determine for themselves that colorants do not migrate to food and thus are not food additives. In a footnote to *Monsanto Co. versus Kennedy*, 613 F.2d 947, 956 (1979), the court concluded that the limited authority to determine that a substance is not a food additive, even though it comes within the strict literal terms of the statutory definition of a food additive, " * * * is an area of decision by its nature committed to the informed discretion of the Commissioner [of FDA]." Thus, only FDA has the authority to determine if specific uses of a food-contact colorant involve minimal migration and are not of regulatory concern.

2. One comment disagreed with the listing in the tentative final rule of chromium oxide green and zinc chromate as colorants. The comment stated that "these materials are considered to be carcinogenic with respect to the OSHA Hazard Communication Standard 1910.1200." The comment expressed concern that FDA should consider this fact, and that confusion will result between FDA and the Occupational Safety and Health Administration (OSHA) if FDA decides that these colorants are permitted for use in food-contact polymers.

FDA has reviewed OSHA's regulation that was mentioned in the comment, § 1910.1200 Hazard Communication (29 CFR 1910.1200), and has found no listings for chromium oxide green or zinc chromate as carcinogens. However, the agency has found in the *Federal Register* a proposed rule on air contaminants, dated June 7, 1988 (53 FR 20960), and a subsequent final rule on this subject, dated January 19, 1989 (54 FR 2332), in which OSHA discussed the potential carcinogenicity of chromic acid, chromates, and zinc chromates. OSHA concluded that further assessment of the available studies was needed to resolve the complex scientific issues regarding the carcinogenicity of the various forms of chromates.

FDA contacted OSHA concerning its final rule, and OSHA confirmed that this position is applicable to chromic acid, chromates, and zinc chromates and remains unchanged (Ref. 1). OSHA and FDA agreed, however, that the OSHA documents address only the potential carcinogenicity of chromium compounds from inhalation exposure. While the documents do not cite any evidence of

carcinogenicity of trivalent chromium compounds, such as chromium oxide green, they do state that zinc chromate, an insoluble form of hexavalent chromium, has been associated with lung cancer in human epidemiological studies of chromate ore workers. The documents establish a ceiling limit for the inhalation exposure of chromic acid and chromates of 0.1 milligram per cubic meter (measured as chromium oxide (CrO_3)).

FDA has concluded its own review of the available scientific literature on the toxicity and potential carcinogenicity of chromium and its compounds (Ref. 2). This review revealed that trivalent chromium is an essential trace element for human nutrition in amounts of 50 to 200 micrograms per day. The agency found no evidence in the available scientific studies that either trivalent chromium compounds, such as chromium oxide green, or elemental chromium are carcinogenic in humans or animals by repeated oral ingestion or by inhalation. In regard to hexavalent chromium compounds, especially those of low water solubility (i.e., zinc chromate), the agency found that human epidemiological studies do associate prolonged, repeated inhalation of relatively high concentrations of some of these compounds with the induction of cancer to the respiratory tract (Refs. 2 and 3). However, the agency finds that the carcinogenicity of these hexavalent chromium compounds by inhalation has no relevance to cancer resulting from oral exposure (Ref. 4). Furthermore, from a review of reports prepared by other government and international organizations (Environmental Protection Agency, National Academy of Sciences/National Research Council, Agency for Toxic Substances and Disease Registry, World Health Organization, and International Agency for Research on Cancer), the agency finds that available data on repeated oral ingestion of hexavalent chromium compounds by animals do not provide a basis on which to conclude that these substances are carcinogenic by ingestion (Ref. 2).

Based on the available scientific studies, FDA concludes that the data do not establish that chromium oxide green or zinc chromate are carcinogenic by oral exposure. Therefore, the agency is not modifying this final rule based upon the concerns expressed in this comment.

3. Three comments requested that the agency make clear that the listing of phthalocyanine blue (pigment blue 15, crystallizing α -form)¹ as a colorant in

the tentative final rule includes the use of pigment blue 15:1 (noncrystallizing α -form), 15:2 (noncrystallizing, nonflocculating α -form), 15:3 (noncrystallizing β -form), and 15:4 (noncrystallizing, nonflocculating β -form), which have the same Colour Index (C.I.) No. 74160. The comments submitted published information demonstrating that these pigment blue 15 colorants all have the same empirical formula ($\text{C}_{32}\text{H}_{16}\text{N}_8\text{Cu}$), the same Chemical Abstracts Service Registry Number (CAS Reg. No.) 147-14-8, and the same structural formula, and that the variations in color are based only on the different crystalline and physical forms of the substance.

FDA has reviewed the information provided by these comments. Based on the evidence submitted, the agency finds that the various shades of pigment blue 15, resulting from the different crystalline and physical forms of this pigment, do have identical empirical and structural formulas and are identified by the same CAS Reg. No. Because the empirical and structural formulas are the same for pigment blue 15:1, 15:2, 15:3, and 15:4 and phthalocyanine blue, and because phthalocyanine blue is a regulated colorant² for which the agency has no toxicological concern, FDA concludes that all these colorants with the common C.I. No. 74160 and with CAS Reg. No. 147-14-8 are safe for use as colorants for food-contact polymers. Therefore, the agency has included the additional names of these colorants in § 178.3297.

4. Two comments raised issues regarding the use of furnace carbon black. One of these comments disagreed with the statement in the tentative final rule that FDA has not received any new information since 1972 to resolve its concerns over the presence of carcinogenic polycyclic aromatic hydrocarbons in furnace black. The comment stated that the agency has a food additive petition and a color additive petition that provide information demonstrating that the level of polycyclic aromatic hydrocarbons in

forms differ in the physical packing of the individual molecules within the crystal.

² Phthalocyanine blue is currently regulated for use in resinous and polymeric coatings under 21 CFR 175.300, in paper and paperboard for contact with aqueous and fatty foods under 21 CFR 176.170, in paper and paperboard for contact with dry food under 21 CFR 176.180, in ethylene-vinyl acetate copolymers under 21 CFR 177.1350, in melamine-formaldehyde resins for molded articles under 21 CFR 177.1460, in polyurethane resins under 21 CFR 177.1680, in resin-bonded filters under 21 CFR 177.2260, in rubber articles intended for repeated use under 21 CFR 177.2600, and in medical devices under 21 CFR 74.3045.

¹ Phthalocyanine blue has two crystalline forms or modifications, referred to as α and β . These

furnace black is not necessarily higher than the level in channel black. The comment urged FDA to develop specifications for acceptable levels of polycyclic aromatic hydrocarbons in both types of carbon black, rather than to continue to limit their use based upon their method of production. The second comment urged FDA to allow the use of furnace black in a manner that is consistent with the use permitted by the U.S. Department of Agriculture (USDA). The comment supplied a copy of an industry trade association bulletin, dated November 8, 1979, that states that USDA does not object to the use of furnace black as a component of printing inks when used, with certain restrictions, on the outer (nonfood-contact) surface of meat and poultry packaging materials.

FDA disagrees with the first comment. Although the agency has received two petitions (7C0208 and 6B3901) for furnace black materials, the materials that are the subjects of the petitions are high purity furnace blacks that the petitioners claim contain substantially lower levels of polycyclic aromatic hydrocarbon residues than unpurified furnace blacks. One of these petitions proposes the use of this black color additive in cosmetics, including eye area use. The other petition is requesting use of this black colorant in food packaging materials. FDA is currently reviewing these petitions and has not yet determined whether the data in the petitions are adequate to resolve the agency's safety concerns, expressed in the April 6, 1988 tentative final rule, about the presence of polycyclic aromatic hydrocarbons in high purity furnace black. If the agency finds that high purity furnace black is safe for the petitioned uses, it will establish specifications for the colorant, allowing the use of only those furnace blacks that are of high purity.

With respect to the second comment, the agency has often advised ink manufacturers and users that the components of inks are not expected to migrate to food when the inks are used on the exterior of food packages, and that the compounds would, therefore, not require FDA approval as food additives. Thus, FDA's position on the use of ink components, including furnace black, has been consistent with the USDA position on the use of furnace black in printing inks for the outer surface of meat and poultry packaging materials. However, the agency is now aware of data demonstrating that components of inks used on the exterior of food packages may migrate to food under certain circumstances (Ref. 5).

Furthermore, the agency has been apprised of the fact that consumers may at times invert printed packages such as bread bags and use them for further food storage. This direct contact of the printed surface with food increases the potential for migration of ink components. The agency intends to review the use of ink components on the exterior of food packages, their migration behavior, and its position on this issue in the future.

5. One comment requested that the list of colorants in the final rule include the color additives FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6.

In the tentative final rule, although FDA did not specifically list these or other permanently listed color additives that are authorized for direct use in food in the list of colorants, it amended § 178.3297 by adding a new paragraph to state that color additives permanently listed for use in foods may also be used as colorants for food-contact polymers. The agency is retaining this authorization in the final rule. Therefore, FDA has not changed the final rule in response to this comment. (The provisional listing of FD&C Red No. 3 for use in cosmetics and externally applied drugs and all uses of the lakes of FD&C Red No. 3 was terminated on January 29, 1990, as announced in the *Federal Register* of February 1, 1990 (55 FR 3516). FDA is currently considering the withdrawal of the permanent listings of FD&C Red No. 3 in food and ingested drugs.)

III. Environmental Impact and Comments on the Environmental Issues Raised by the April 6, 1988 Tentative Final Rule

In the tentative final rule, FDA requested environmental assessments from those persons interested in the expanded use of six identified colorants and in the use of color additives that are used in ingested drugs and cosmetics, and the lakes of these color additives, as colorants for polymers. In response to this request, four companies and a trade association submitted comments to the agency.

6. Four companies submitted individual abbreviated environmental assessments for the expanded uses of phthalocyanine green, quinacridone red, and cobalt aluminate and for the use of D&C Red No. 7 and its lakes as colorants in all food-contact polymers.

The agency has reviewed the information submitted for phthalocyanine green, quinacridone red, and D&C Red No. 7 and its lakes and finds that the data required for an abbreviated environmental assessment

were provided. This information provides an adequate basis on which to evaluate the environmental impact of the expanded use of phthalocyanine green and quinacridone red and the use of D&C Red No. 7 and its lakes as colorants in all polymers that contact food. FDA has considered the potential environmental effects of these actions and concludes that the actions will not have a significant impact on the human environment, and that environmental impact statements are not required. The agency's findings of no significant impact and the evidence supporting those findings, contained in the individual environmental assessments, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FDA is, therefore, removing the limitations on the use of phthalocyanine green and quinacridone red that were included in the tentative final rule and is listing D&C Red No. 7 and its lakes for use as colorants in polymers in the colorants final rule.

The information for cobalt aluminate was submitted on December 13, 1990 and is under review by the agency. The agency has decided not to delay publication of this final rule to complete this review. When the data required for an abbreviated environmental assessment have been provided, FDA will evaluate the environmental impact of the expanded use of cobalt aluminate as a colorant in all polymers. If the agency concludes that this action will not have a significant impact on the human environment, and that an environmental impact statement is not required, it will remove the limitation on the use of cobalt aluminate as a colorant for polymers and will announce the action in a separate document in the *Federal Register*.

7. Another comment disagreed with the agency's statement that FDA does not have environmental data to assess the impact of the expanded use of chromium oxide green, cobalt aluminate, phthalocyanine green, quinacridone red, zinc carbonate, and zinc oxide. This comment stated that the agency should do a worst-case environmental assessment of the expanded use of these colorants based on the environmental data that provided the basis for their regulated uses.

An additional comment from a trade association stated that it has been informed that chromium oxide green, cobalt aluminate, phthalocyanine green, quinacridone red, zinc carbonate, and zinc oxide have been widely used as colorants by its members. This comment

asserted that these and other widely used colorants should, therefore, be exempted from the environmental data requirements requested in the tentative final rule.

FDA rejects these comments. As stated in the tentative final rule, the agency finds that it does not have any data to assess the worst-case environmental impact of the expanded use of the six colorants in food-contact polymers. FDA listed the limited uses of these six colorants before there was a need to conduct an environmental review under the National Environmental Policy Act (NEPA), and thus, no data were submitted on the environmental impact of the use of these substances when they were regulated as colorants in polymers. Therefore, the agency has no basis on which to conduct a worst-case assessment on the expanded use of these six colorants in food-contact polymers.

Although one comment suggested that these colorants are in wide use, uses beyond those allowed in the regulations are new uses. As stated in the tentative final rule, the agency cannot exempt new uses for colorants in polymers from environmental review, nor can it exempt uses of colorants that may have been used without FDA approval.

The agency is, therefore, denying the request made by these comments that it authorize the expanded use of chromium oxide green, cobalt aluminate, zinc carbonate, and zinc oxide as colorants in polymers without the environmental data requested in the tentative final rule. Further, except for D&C Red No. 7 and its lakes, the agency is not listing any color additives that are used in ingested drugs and cosmetics, or the lakes of any of these color additives, as colorants in polymers that contact food. No environmental assessments were submitted on the use of these color additives as colorants as requested in the tentative final rule, and the agency does not have data in its files to assess the environmental impact of the use of these additives as colorants for polymers.

IV. Economic Impact and Comments on the Economic Issues Raised in the April 6, 1988 Tentative Final Rule

In accordance with the Regulatory Flexibility Act, the agency considered the potential effects that this regulation would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency determined that no significant economic impact on a substantial number of small entities would derive from this action. In

response to this action, the agency received one comment.

8. The comment asserted that there will be a significant economic impact on the industry if environmental impact assessments must be submitted for the expanded uses of the six colorants (phthalocyanine green, quinacridone red, chromium oxide green, cobalt aluminate, zinc carbonate, and zinc oxide) that had limited uses in the tentative final rule.

In considering the expanded uses of the six colorants listed in the tentative final rule, the agency is required by NEPA to determine the environmental impact of these new uses. The agency stated this fact in the tentative final rule and advised that it did not have the data needed to make this determination. FDA does not have the authority to exempt the expanded uses of the six colorants from the NEPA requirement for environmental analyses. Thus, as required by law, the six colorants must have environmental impact assessments before they can be approved for expanded uses. The requirements of NEPA do not, however, override the need for an economic impact analysis, and the agency has completed one for this final rule.

The agency has carefully reviewed and considered the potential economic effects of this final rule and, on the basis of the available evidence, concludes that no significant economic impact on a substantial number of small entities would derive from this action. The agency has received no information that would cause it to alter this determination. The agency's finding of no significant impact on a substantial number of small entities, and the evidence supporting this finding, are contained in the threshold assessment which may be seen in the Dockets Management Branch (address above).

V. Conclusions

Based on the comments and the environmental assessments that were received, FDA is providing for the use of the colorants that were the subjects of the 1972 petitions, for additional uses of phthalocyanine green and quinacridone red, for the use of D&C Red No. 7 and its lakes, and for the use of additional shades of phthalocyanine blue in food-contact polymers. The agency is also consolidating the listing of colorants for polymers by transferring a number of colorants from other regulations that provide for their use in food-contact polymers to a single regulation on colorants, 21 CFR 178.3297.

Further, FDA is modifying § 178.3297(c) to remove the offer of copies of the analytical methods and

extraction procedures, because the extraction limits that were in § 178.3297 (for chromium oxide green, phthalocyanine green, and quinacridone red) are being removed, as stated in comment six of the tentative final rule. Section 178.3297(c) is also amended to inform interested parties of the availability of extraction testing guidelines for colorants from FDA.

The agency is also including the following nonsubstantive editorial corrections in this final rule:

(1) 4,4'-Bis (4-anilino-6-methylethanolamine- α -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt, was listed as a colorant for textiles and textile fibers under former § 121.2535(d)(5)(ii). However, during the recodification of Title 21 in 1977, this substance was inadvertently omitted from new § 177.2800 textiles and textile fibers (21 CFR 177.2800) for this use. Therefore, FDA is correcting this omission by alphabetically adding this colorant to the list of substances under § 178.3297(e).

(2) Section 178.3550 *Kaolin-modified* (21 CFR 178.3550) is being removed, and the use of modified kaolin as a colorant in olefin polymers is being transferred to new § 178.3297(e). This transfer was inadvertently omitted in the tentative final rule.

(3) Phthalocyanine blue is being removed from § 177.2260(d)(5) (21 CFR 177.2260(d)(5)). This deletion was not made clear in the tentative final rule. This colorant is listed in § 178.3297 without limitations. In § 177.2260, paragraph (d)(5) is also being amended to make clear that all applicable colorants listed in § 178.3297 may be used in resin-bonded filters.

(4) In § 177.2250 *Filters, microporous polymeric* (21 CFR 177.2250), paragraph (d) is being revised in this final rule to make clear that colorants in § 178.3297 may be used to color microporous polymeric filters. This change was inadvertently omitted in the tentative final rule.

(5) In the listing for ultramarines in § 178.3297, specific reference in the tentative final rule to the various shades of this colorant has been dropped from the "Substances" column in this final rule because these shades are included in the "Limitations" column under the § 73.2725 cross-reference.

(6) The format for listed colorants in § 176.170 that was previously adopted in the tentative final rule is being changed. In this final rule, these colorants are listed together in § 176.170 under a heading entitled "Colorants". This format is preferred because it will allow for ready recognition of colorants used

as components of paper and paperboard in contact with aqueous and fatty food.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 30, 1991 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this 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.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of Telephone Conversations on April 12, 1990, between Sandra L. Varner, FDA, and Susan Flemming, OSHA, and Ed Stein, OSHA, "Chromium oxide green and zinc chromate (FAP's 6R1862, 8R2288, 0R2512, 0R2534, 1R2641)."

2. Memorandum dated July 22, 1988, from the Standards and Monitoring Branch to the

Contaminants Group, "General toxicology of chromium and its compounds."

3. Environmental Protection Agency, "Health Assessment Document for Chromium Final Report," EPA-600/8-83-014F, Research Triangle Park, NC, August, 1984.

4. Environmental Protection Agency, "Chromium Health Advisory," Office of Drinking Water, Washington, DC, March 31, 1987.

5. Castle, L., A. Mayo, and J. Gilbert, "Migration of Plasticizers from Printing Inks Into Foods," Food Additives and Contaminants, 6:437-443, 1989.

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

Part 176

Food additives, Food packaging.

Part 177

Food additives, Food packaging.

Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 175, 176, 177, and 178 are amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 175.300 is amended by revising paragraph (b)(3)(xxvi) to read as follows:

§ 175.300 Resinous and polymeric coatings.

(b) * * *

(3) * * *

(xxvi) Colorants used in accordance with § 178.3297 of this chapter.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

3. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 376).

4. Section 176.170 is amended in paragraph (b)(1) by adding "(xxvi)" after "(xx)" and in paragraph (b)(2) by adding a new heading entitled "Colorants:" and

27 new entries to the end of the existing table under the headings "List of substances" and "Limitations" to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

List of substances	Limitations
Colorants:	
Aluminum	For use as a colorant only.
Aluminum hydrate	Do.
Aluminum and potassium silicate (mica)	Do.
Aluminum mono-, di-, and tri-stearate	Do.
Aluminum silicate (China clay)	Do.
Barium sulfate	Do.
Bentonite	Do.
Bentonite, modified with dimethyldioctadecylammonium ion	Do.
Burnt umber	Do.
Calcium carbonate	Do.
Calcium silicate	Do.
Calcium sulfate	Do.
Carbon black (channel process)	Do.
Cobalt aluminate	Do.
Diatomaceous earth	Do.
Iron oxides	Do.
Magnesium oxide	Do.
Magnesium silicate (talc)	Do.
Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8)	Do.
Raw sienna	Do.
Silica	Do.
Tartrazine lake (certified FD&C Yellow No. 5 only)	Do.
Titanium dioxide	Do.
Titanium dioxide-barium sulfate	Do.
Titanium dioxide-magnesium silicate	Do.
Zinc carbonate	Do.
Zinc oxide	Do.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

5. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

6. Section 177.1350 is amended by revising paragraph (a)(3) to read as follows:

§ 177.1350 Ethylene-vinyl acetate copolymers.

(a) * * *

(3) Substances identified in § 175.300(b)(3) (xxv), (xxvii), (xxx), and (xxxiii) of this chapter, and colorants

used in accordance with § 178.3297 of this chapter.

7. Section 177.1460 is amended in the table in paragraph (b) by removing the entry "Pigments and colorants identified in * * *" and by alphabetically adding a new entry under the heading "List of substances" to read as follows:

§ 177.1460 Melamine-formaldehyde resins in molded articles.

(b) * * *

List of substances	Limitations
Colorants used in accordance with § 178.3297 of this chapter.	.

8. Section 177.1520 is amended in the table in paragraph (b) by removing the entry "7-(2H-Naphtho[1,2-d]-triazol-2-yl)-3-phenylcoumarin * * *" and by alphabetically adding a new entry under the heading "Substance" to read as follows:

§ 177.1520 Olefin polymers.

(b) * * *

Substance	Limitations
Colorants used in accordance with § 178.3297 of this chapter.	.

9. Section 177.1680 is amended in the table in paragraph (b) by removing the entries "Phthalocyanine blue (C.I. pigment blue 15, C.I. No. 74160)" and "Ultramarine blue" and by alphabetically adding a new entry under the heading "List of substances" to read as follows:

§ 177.1680 Polyurethane resins.

(b) * * *

Substances	Limitations
Aluminum	
Aluminum hydrate	
Aluminum and potassium silicate (mica)	
Aluminum mono-, di-, and tristearate	
Aluminum silicate (China clay)	
Barium sulfate	
Bentonite	
Bentonite, modified with 3-dimethyldioctadecylammonium ion	
4,4'-Bis(4-anilino-6-diethanolamine- α -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, For use only in the textile fibers specified in § 177.2800 of this chapter.	
disodium salt.	

List of substances	Limitations
Colorants used in accordance with § 178.3297 of this chapter.	.

10. Section 177.2250 is amended by revising paragraph (d) to read as follows:

§ 177.2250 Filters, microporous polymeric.

(d) The microporous polymeric filters may be colored with colorants used in accordance with § 178.3297 of this chapter.

11. Section 177.2260 is amended by revising paragraph (d)(5) to read as follows:

§ 177.2260 Filters, resin-bonded.

(d) * * *

(5) *Colorants:* Colorants used in accordance with § 178.3297 of this chapter.

12. Section 177.2600 is amended by revising paragraph (c)(4)(vi) to read as follows:

§ 177.2600 Rubber articles intended for repeated use.

(c) * * *

(4) * * *

(vi) *Colorants.* Colorants used in accordance with § 178.3297 of this chapter.

13. Section 177.2800 is amended in the table in paragraph (d)(5) under "(ii) Adjuvant substances" by removing entries "4,4'-Bis(4-anilino-6-diethanolamine- α -triazin-2-ylamino)-2,2'-stilbene-disulfonic acid, disodium salt." and "7-(2H-naphtho[1,2-d]triazol-2-yl)-3-phenylcoumarin * * *" and by alphabetically adding a new entry under "(ii) Adjuvant substances" to read as follows:

§ 177.2800 Textiles and textile fibers.

(d) * * *

(5) * * *

List of substances	Limitations
(ii) * * *	
Colorants used in accordance with § 178.3297 of this chapter.	.

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

14. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drugs, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

15. Section 178.3297 is amended by revising paragraph (c), by adding new paragraph (d), and by alphabetically adding new entries to the table in paragraph (e) to read as follows:

§ 178.3297 Colorants for polymers.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Center for Food Safety and Applied Nutrition, Division of Food and Color Additives (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(d) Color additives and their lakes permanently listed for direct use in foods, under the provisions of the color additive regulations in parts 73 and 74 of this chapter, may also be used as colorants for food-contact polymers.

(e) * * *

Substances	Limitations
4,4'-Bis(4-anilino-6-methylethanamine- α -triazin-2-ylamino)-2,2'-stilbene disulfonic acid, disodium salt	Do.
Burnt umber	
Calcium carbonate	
Calcium silicate	
Calcium sulfate	
Carbon black (channel process, prepared by the impingement process from stripped natural gas)	
Chromium oxide green, Cr ₂ O ₃ (C.I. pigment green 17, C.I. No. 77268)	For use only in olefin polymers complying with § 177.1520 of this chapter.
Cobalt aluminate	For use only:
	1. In resinous and polymeric coatings complying with § 175.300 of this chapter.
	2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter.
	3. Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter.
	4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter.
	5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.
D&C Red No. 7 and its lakes	
Diatomaceous earth	
Iron oxides	
Kaolin-modified, produced by treating kaolin with a reaction product of isopropyl titanate and oleic acid in which 1 mole of isopropyl titanate is reacted with 1 to 2 moles of oleic acid. The reaction product will not exceed 8 percent of the modified kaolin. The oleic acid used shall meet the requirements specified in § 172.860 of this chapter.	For use only in olefin polymers complying with § 177.1520 of this chapter at levels not to exceed 40 percent by weight of olefin polymer.
Magnesium oxide	
Magnesium silicate (italc)	
7-(2H-Naphtho[1,2-d]triazol-2-yl)-2-phenylcoumarin (CAS Reg. No. 3333-62-8) having a melting point of 250 °C to 251 °C and a nitrogen content of 10.7 to 11.2 percent.	For use as an optical brightener only in:
	1. Olefin polymers complying with § 177.1520 of this chapter only at levels such that the product of concentration of the optical brightener (expressed in parts per million by weight of the olefin polymer) multiplied by the thickness of the olefin polymer (expressed in thousandths of an inch and limited to no more than 0.400 inch) shall not exceed 500; provided that the level of the brightener shall not exceed 20 parts per million by weight of the olefin polymer, and further that the olefin polymers shall comply with specifications for items 1.1, 2.1, 3.1, 3.3, and 4 of § 177.1520(c) of this chapter. The polymer may be used under the conditions described in § 176.170(c) of this chapter, Table 2, under conditions of use E, F, and G.
	2. Polyethylene terephthalate specified in § 177.2800(d)(5)(i) of this chapter at a level not to exceed 0.035 percent by weight of the finished fibers.
Phthalocyanine blue (C.I. pigment blue 15, 15:1, 15:2, 15:3, and 15:4; C.I. No. 74160; CAS Reg. No. 147-14-8)	
Phthalocyanine green (C.I. pigment green 7, C.I. No. 74260)	
C.I. Pigment red 38 (C.I. No. 21120)	For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber article.
Quinacridone red (C.I. Pigment violet 19, C.I. No. 73900)	
Sienna (raw and burnt)	
Silica	
Tartrazine lake (certified FD&C Yellow No. 5 only)	For use only as a component of resinous and polymeric coatings complying with § 175.300 of this chapter.
Titanium dioxide	
Titanium dioxide-barium sulfate	
Titanium dioxide-magnesium silicate	
Ultramarines	As identified in § 73.2725 of this chapter.
Zinc carbonate	For use only:
	1. In resinous and polymeric coatings complying with § 175.300 of this chapter.
	2. Melamine-formaldehyde resins in molded articles complying with § 177.1460 of this chapter.
	3. Xylene-formaldehyde resins condensed with 4,4'-isopropylidene diphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter.
	4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter.
	5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.
Zinc chromate	For use only in rubber articles for repeated use complying with § 177.2600 of this chapter; total use is not to exceed 10 percent by weight of rubber articles.
Zinc oxide	For use only:
	1. In resinous and polymeric coatings complying with § 175.300 of this chapter.
	2. Melamine-formaldehyde resins in molded articles complying with § 177.2460 of this chapter.
	3. Xylene-formaldehyde resins condensed with 4,4'-isopropylidene-diphenol-epichlorohydrin epoxy resins complying with § 175.380 of this chapter.
	4. Ethylene-vinyl acetate copolymers complying with § 177.1350 of this chapter.
	5. Urea-formaldehyde resins in molded articles complying with § 177.1900 of this chapter.

§§ 178.3550 and 178.3970 [Removed]

16. Section 178.3550 Kaolin-modified and § 178.3970 Ultramarine blue are removed from subpart D.

Dated: August 22, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-20836 Filed 8-29-91; 8:45 am]

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1308****Schedules of Controlled Substances: Procedures for Removing Certain Anabolic Steroid Products From All or Part of the Controlled Substances Act**

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: This rule describes administrative procedures for removing regulatory control from the manufacture, distribution, and possession of specific products which contain anabolic steroids. The affected products are those which are approved for implantation into animals or those which have no significant potential for abuse. These procedures implement two provisions of the Anabolic Steroids Control Act of 1990 which placed the anabolic steroids into Schedule III of the Controlled Substances Act.

EFFECTIVE DATE: September 30, 1991.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section; Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Enactment of the Anabolic Steroids Control Act of 1990 (ASCA) (title XIX of Pub. L. 101-647) resulted in the addition of the anabolic steroids to Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.) on February 27, 1991. (See 56 FR 5753, February 13, 1991). The ASCA provides regulatory controls and significant penalties for the illegal possession and distribution of anabolic steroids. The ASCA also provides relief from certain regulatory aspects of Schedule III for products which do not contribute to the drug abuse problem. The products which are afforded special treatment under the CSA are those which are expressly intended for administration through implants to cattle or other nonhuman species and

are approved for such use by the Secretary of Health and Human Services and other products which, because of their concentration, preparation, mixture, or delivery system, have no significant potential for abuse. The Administrator of the Drug Enforcement Administration (DEA) proposed procedures by which these products would be identified (56 FR 10845, March 14, 1991). Three parties submitted comments or objections and the sponsors of two products submitted applications in accordance with the proposed regulations. This notice responds to the comments and issues the regulations implementing sections 1902(b) and 1903(a) of the ASCA.

One individual commented on the definition of the term "anabolic steroid." Because the definition is the same as that which is contained in the ASCA and because the definition was published in a notice (56 FR 5753, February 13, 1991) other than the one which proposed the procedures for exempting products from certain regulatory controls, the merits of the comment will not be responded to in this notice.

The Director, Office of Orphan Products Development, Food and Drug Administration, expressed concern that the proposed regulations did not address section 1903(b) of the ASCA. Section 1903(b) deals with drugs for treatment of rare diseases and outlines the provisions which allow the Attorney General to exempt such a drug from any production regulations otherwise issued under the CSA. Review of the legislative history of the ASCA reveals that the language of section 1903(b) is identical to that proposed in a Senate bill which was entitled The Steroid Trafficking Act of 1990. That bill, which was incorporated, in part, into the Anabolic Steroid Control Act of 1990, proposed the placement of anabolic steroids into Schedule II of the CSA. The CSA mandates that production limits be established on the manufacture of Schedule I and II substances. The law which was enacted, the Anabolic Steroids Control Act of 1990 (Title of XIX of Pub. L. 101-647), placed the anabolic steroids in Schedule III of the CSA. Schedule III does not provide for the establishment of production quotas. There is no need to promulgate regulations through which anabolic steroids might be exempted from production regulations which do not apply. Products for treatment of rare diseases will be treated like other products under section 1903(a) of the ASCA.

The Animal Health Institute, the national trade association representing

the manufacturers of animal health products, objected to the adoption of proposed §§ 1308.25 and 1308.26 on the grounds that (a) they are not authorized by the ASCA and (b) they are unnecessary in light of existing regulations in 21 CFR part 522. The position of the DEA is that the proposed sections are in keeping with the ASCA and they are warranted. The language of the ASCA is such that the lawful marketing of anabolic steroid products for implantation into cattle and other nonhuman species is not to be affected by the CSA. It is for that express purpose that the products must be identified to the DEA. Currently, there is no mechanism by which the DEA can identify these products with sufficient particulars to permit implementation of the ASCA. Compliance with 21 CFR part 522, regulations issued by the Food and Drug Administration, does not meet the needs of the DEA. The regulations implementing the ASCA serve to identify those products to which the CSA will not apply unless the products are prescribed, dispensed, or distributed for human use.

In regard to those products which are excluded from the CSA, the ASCA describes them as having been approved by the Secretary for Health and Human Services rather than in the language used in the notice of proposed rulemaking. The issued regulations reflect conformance with the language of the ASCA. Also, the notice of proposed rulemaking did not specify that applications are to be submitted in triplicate. Because the issued regulations do not differ from those which were proposed, except to specify that three copies of an application be submitted, the applications which were submitted in response to the issuance of the notice of proposed rulemaking will be acted on.

The Administrator of the DEA hereby certifies that this rule will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

This rule is not a major rule for purposes of Executive Order (E.O.) 12291 (46 FR 13193, February 17, 1981). Pursuant to sections 3(c)(3) and 3(e) (2) (C) of E.O. 12291, this rule has been submitted for review to the Office of Management and the Budget.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612 and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.