§ 404.939 Presiding officer's decision or certification to Appeals Council.

(a) *Decision.* As soon as practicable after the close of a hearing, the presiding officer shall issue a decision. Such decision shall be based upon the evidence adduced at the hearing or otherwise included in the record (§§ 404.923–404.934). The decision shall be made in writing and contain findings of fact and a statement of reasons in support thereof. A copy of the decision shall be mailed to the parties at their last known addresses. Where appropriate, the presiding officer may certify a case to the Appeals Council after a hearing with a recommended decision.

(b) *Recommended decision in court remand cases.* Where the presiding officer conducts a hearing on a case which has been remanded to the Appeals Council by a court, such case shall be returned to the Appeals Council with a recommended decision (see § 404.950(b)).

13. Section 404.942 is revised to read as follows:

§ 404.942 Case certified to Appeals Council by presiding officer.

(a) *Notice.* When a case has been certified to the Appeals Council by a presiding officer with his recommended decision, the presiding officer shall mail notice of such action with a copy of the recommended decision to the parties at their last known addresses. The parties shall be notified of their right to file with the Appeals Council within 10 days from the date of mailing of the recommended decision, briefs, or other written statements of exceptions or allegations as to applicable fact and law. Upon request of any party made within such 10-day period, a 10-day extension of time for filing such briefs or statements shall be granted and, upon a showing of good cause, such 10-day period may be further extended, as appropriate. Where there is more than one party, copies of such briefs or written statements shall be filed in sufficient number that they may be made available to any party requesting a copy or any other party designated by the Appeals Council. Copies or a statement of the contents of the documents or other written evidence received in evidence in the hearing record, and a copy of the transcript of oral evidence adduced at the hearing, if any, or a condensed statement thereof shall be made available to any party upon request, upon payment of the cost, or if such cost is not readily determinable, the estimated cost thereof, unless for good cause shown, such payment is waived.

(b) *Procedure.* The proceedings before the Appeals Council on certification pursuant to paragraph (a) of this section shall be in accordance with the rules and procedure in § 404.948 and § 404.949. The Appeals Council shall make a decision. Where the Appeals Council determines that additional evidence is required, it may remand the case to the presiding officer for further inquiry into the matters, rehearing, receipt of evidence, and a subsequent initial hearing decision, or a recommended decision to the Appeals Council except where the Appeals Council decides that it can obtain the additional evidence more expeditiously, it will take the appropriate action.

§§ 404.943 and 404.944 [Reserved]

14. Sections 404.943 and 404.944 are revoked and reserved.

15. Section 404.947a is added to read as follows:

§ 404.947a Basis for review of the presiding officer's decision or dismissal by Appeals Council.

(a) The Appeals Council, on its own motion or on request for review, will review a hearing decision or dismissal where:

(1) There appears to be an abuse of discretion by the presiding officer;

(2) There is an error of law;

(3) The presiding officer's action, findings, or conclusions are not supported by substantial evidence; or

(4) There is a broad policy or procedural issue which may affect the general public interest.

(b) Where new and material evidence is submitted with the request for review, the entire record will be evaluated and review will be granted where the Appeals Council finds that the presiding officer's action, findings, or conclusion is contrary to the weight of the evidence currently of record.

16. Section 404.950 is revised to read as follows:

§ 404.950 Decision by Appeals Council or remanding of case.

(a) *Case remanded to presiding officer.* The Appeals Council may remand to the presiding officer for rehearing, receipt of evidence, and decision, any case which it decides to review as provided in § 404.947 and § 404.947a. Where a case is thus remanded, the presiding officer shall initiate such additional proceedings and take such action (under §§ 404.919 through 404.940) as is directed by the Appeals Council in its order of remand. The presiding officer may take any additional action not inconsistent with the order of remand. Upon completion of all action called for by the order of remand and any other action initiated by the presiding officer, the presiding officer shall promptly issue a decision in writing which contains findings of fact and reason in support thereof. A copy of the decision shall be mailed to each party at his last known address.

(b) *Court remanded case.* Where a case has been remanded by a court for further consideration, the Appeals Council may proceed to make the decision or it may, in turn, remand the case to a presiding officer with directions to return the case upon completion of the necessary action to the Appeals Council with a recommended decision for decision by the Appeals Council.

(c) *Decision on review.* The Appeals Council will issue a decision affirming, modifying, or reversing the hearing decision or issue an order to vacate such decision and remand the case to a presiding officer for rehearing and decision. A decision of the Appeals Council shall be based upon the evidence received into the hearing record and such further evidence as the Appeals Council may receive, as provided in §§ 404.942, 404.948, and 404.949. This decision shall be made in writing and contain findings of fact, and a statement of reasons. A copy of the decision shall be mailed to each party at his last known address.

17. Sections 404.918, 404.919, 404.922, 404.925, 404.926, 404.927, 404.929, 404.931, 404.935, 404.936, 404.937, 404.937a, 404.938, 404.940, 404.941, 404.945, 404.946, 404.947, 404.948, 404.949, 404.951, 404.952, 404.954, 404.955, 404.956, 405.722, 405.730, 405.740, 405.741, 405.747, and 405.750 are amended by deleting the words "administrative law judge" wherever they appear and inserting in lieu thereof "presiding officer."

18. Sections 404.917, 404.918, 404.920, 404.928, 404.937, 404.946, and 404.953 are amended by deleting "Administration" wherever it appears and inserting in lieu thereof "Social Security Administration."

§ 404.956 [Amended]

19. In § 404.956(b), the term "hearing examiner" is revised to read "presiding officer."

[FR Doc.76-34568 Filed 11-22-76;8:45 am]

Title 21—Food and Drugs

CHAPTER 1—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Subchapter A—General

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

Changes in Service Rates

Correction

In FR Doc. 33879, appearing at page 50420, in the issue of Tuesday, November 16, 1976, on page 50420 delete the words "or before" in column 1, 1st paragraph, next to the last line and in column 2, last paragraph, next to the last line.

SUBCHAPTER A—GENERAL

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 76N-0385]

NEW DRUGS

Reassignment of Responsibility for Urokinase

The Food and Drug Administration (FDA) is reassigning from the Bureau of Drugs to the Bureau of Biologics the responsibility for regulating urokinase products, and reminding all interested persons that the Bureau of Biologics is also responsible for regulating all streptokinase and streptodornase products; effective on November 23, 1976.

The Commissioner of Food and Drugs indicated by notice published in the FEDERAL REGISTER of July 25, 1975 (40 FR 31311), that he was reviewing those products that historically have been

regulated by the Bureau of Drugs and the Bureau of Biologics (and its predecessor organization) to determine if there is a need for some reassignment of responsibility for such products to achieve the maximum administrative efficiency. As a result of this review, reassignment of responsibility for certain products has already taken place between the two bureaus. Radioactive biological products were reassigned to the Bureau of Drugs as a result of regulations published in the FEDERAL REGISTER of July 25, 1975. The Commissioner reassigned to the Bureau of Biologics the responsibility for containers for the collection or processing of blood and blood components by regulations published in the FEDERAL REGISTER of August 13, 1975 (40 FR 33971).

This document, the third document reassigning responsibility for certain human drugs between the two bureaus, transfers responsibility for urokinase products.

Urokinase is an enzyme isolated from human urine or tissue cultures of human kidney. It does not act on fibrinogen or fibrin, but through cleavage of a peptide bond(s), converts the circulating plasma proenzyme, plasminogen, to the proteolytic enzyme, plasmin. One of the physiologic functions of plasmin is digestion of fibrin, leading to lysis (destruction) of blood clots. The conversion of plasminogen to plasmin is also accomplished by various plasma and tissue activators, and indirectly by the bacterial product, streptokinase. The latter is not an enzyme but interacts stoichiometrically with plasminogen or plasmin to yield a complex capable of functioning enzymatically to convert plasminogen to plasmin.

Urokinase is a new drug as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)) and is therefore subject to the new drug provisions of the act. Although no new drug applications (NDA's) have been approved for this product, several sponsors have submitted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) to FDA. These IND's have been the responsibility of the Bureau of Drugs.

Streptokinase and streptokinase-streptodornase, products with an action similar to urokinase, on the other hand, have been controlled by the Bureau of Biologics or its predecessor organization for more than 20 years. They are both biological products subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262) because they are considered analogous to a virus as defined in § 600.3(h)(5)(i) (21 CFR 600.3(h)(5)(i)). Both products are produced by cultivating a selected strain of streptococcus, a bacterium that is actually or potentially infectious, in an appropriate culture medium. Unlike streptokinase and streptokinase-streptodornase, urokinase does not fall within the definition of a biological product and is thus not subject to section 351 of the Public Health Service Act.

The Commissioner concludes that because of the similarity of action of urokinase and streptokinase products, both products should be regulated by the same bureau. He concludes that the Bureau of Biologics should have this responsibility in view of their expertise in the field of blood and blood products.

As a result of this decision to transfer responsibility for urokinase products from the Bureau of Drugs to the Bureau of Biologics, all active IND's and any pending NDA's for urokinase have been transferred to the Bureau of Biologics. All future IND's and NDA's for urokinase products and any amendments or supplements to them should be sent to the Bureau of Biologics.

Accordingly, the Commissioner concludes that §§ 312.1 and 314.1(a) (21 CFR 312.1 and 314.1(a)) should be amended to require that IND's and NDA's for urokinase products be submitted to the Buruea of Biologics instead of the Bureau of Drugs. Recognizing that responsibility for other products may be reassigned in the future, the Commissioner is adding new paragraph (j) to § 312.1 to list the products that have been reassigned and the bureau responsible for them. As a result of establishing this new paragraph, the Commissioner finds that it is appropriate to amend paragraph (g) of § 312.1 by deleting reference to the two types of products that have already been reassigned and are currently included in this section. Likewise, paragraph (a) of § 314.1 is also amended to make the future addition of any reassigned products easier.

To provide for this reassignment of responsibility for urokinase products, the Commissioner is also making appropriate revisions to Part 5 (21 CFR Part 5), Delegations of Authority and Organization. In addition to these changes, the Commissioner is amending § 5.39 (21 CFR 5.39) to provide for revised delegations relating to authority to terminate exemptions for IND's pertaining to ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components and radioactive biological products.

Further redelegation of the authority redelegated hereby is not authorized. Authority redelegated hereby to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting" or unless not legally permissible.

Although the responsibility for streptokinase and streptokinase-streptodornase products remains unchanged, the Commissioner advises all interested persons that such products are biological products subject to section 351 of the Public Health Service Act and are regulated by the Bureau of Biologics. As indicated previously, such products have been regulated under section 351 of the Public Health Service Act for more than 20 years. Therefore, all IND's and license applications for such products should be sent directly to the Bureau of Biologics. Recently, two IND's for streptokinase products were submitted to the Bureau of Drugs. Those IND's have been transferred to the Bureau of Biologics, and their sponsors should submit any subsequent supplements or amendments to the Bureau of Biologics.

Since the amendments pertain solely to internal administrative designation of responsibility concerning urokinase products, notice, public procedure, and delayed effective date are necessary for their promulgation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701 (a), 52 Stat. 1052–1053 as amended, 1055 (21 U.S.C. 355, 371(a))) and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. In § 5.30 by revising paragraphs (a) and (b) to read as follows:

§ 5.30 Delegations regarding approval of new drug applications and supplements thereto for drugs for human use.

(a) The Director, Deputy Director, and Associate Director for New Drug Evaluation of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new-drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to sec. 505 of the Federal Food, Drug, and Cosmetic Act, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(1) The Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; and Oncology and Radiopharmaceutical Drug Products of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications which are for drugs for human use and have been submitted pursuant to §§ 314.1(c) and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(2) The Associate and Deputy Associate Director for Drug Monographs and the Director of the Division of Generic

Drug Monographs of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs regarding the approval of abbreviated new drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to §§ 314.1(f) and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

2. In § 5.31, by revising read as follows:

§ 5.31 Delegations regarding issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and supplements thereto for drugs for human use.

(a) The Director and Deputy Director of the Bureau of Drugs are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto which are for drugs for human use and have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, except those pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components for which authority has been delegated in paragraph (b) of this section, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to issue notices of opportunity for hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto which are for drugs for human use pertaining to urokinase products and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components and which have been submitted pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and §§ 314.1 and 314.8 of this chapter, and to issue notices of withdrawal of approval when opportunity for hearing has been waived.

3. In § 5.39, by revising paragraphs (a) and (b) to read as follows:

§ 5.39 Delegations regarding termination of exemptions for new drugs for investigational use in human beings or in animals.

(a) The Director and Deputy Director of the Bureau of Drugs are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in animals under § 312.9 of this chapter, except those pertaining to biological products (unless the product is also a radioactive drug), urokinase products, and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components for which authority has been delegated in paragraph (b) of this section. The Associate Director and Deputy Associate Director for New Drug Evaluation and the Directors of the Divisions of: Anti-Infective Drug Products; Cardio-Renal Drug Products; Surgical-Dental Drug Products; Metabolism and Endocrine Drug Products; Neuropharmacological Drug Products; and Oncology and Radiopharmaceutical Drug Products of the Bureau of Drugs are authorized to notify sponsors and invite correction before termination action on such exemptions.

(b) The Director, Deputy Director, and Associate Director of the Bureau of Biologics are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the termination of exemptions for new drugs for investigational use in human beings under § 312.1 and in animals under § 312.9 of this chapter pertaining to nonradioactive biological products subject to the licensing provisions of section 351 of the Public Health Service Act (42 U.S.C. 262), nonradioactive urokinase products, and ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components.

* * * * *

PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

4. In § 312.1, by revising paragraph (g) and by adding new paragraph (j) to read as follows:

§ 312.1 Conditions for exemption of new drugs for investigational use.

* * * * *

(g) A "Notice of Claimed Investigational Exemption for a New Drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended (42 U.S.C. 201 et seq.)) shall be submitted initially to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014. Amendments of or supplements to such notice, and progress reports, consultations, or other communications with regard to the investigation shall be directed to the same office to which the original notice was sent. A sponsor for a "Notice of Claimed Investigational Exemption for a New Drug" submitted to the Bureau of Biologics shall substitute in reading this section "Bureau of Biologics" for "Bureau of Drugs" wherever it appears.

* * * * *

(j) As a result of a reassignment of responsibility for certain human drugs between the Bureau of Drugs and the Bureau of Biologics, a "Notice of Claimed Investigational Exemption for a New Drug" for the following products, or groups of products, shall be submitted to the Food and Drug Administration as follows:

(1) Biological products for human use which are also radioactive drugs are not deemed to be subject to the licensing provisions of the Public Health Service Act in accordance with § 310.4 of this chapter, and a "Notice of Claimed Investigational Exemption for a New Drug" which pertains to radioactive biological products shall be submitted to the Division of Oncology and Radiopharmaceutical Drug Products, Bureau of Drugs, 5600 Fishers Lane, Rockville, MD 20852.

(2) Ingredients packaged together with containers intended for the collection, processing, or storage of blood or blood components shall be submitted to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014.

(3) Urokinase products shall be submitted to the Director, Bureau of Biologics, at the address given in paragraph (j)(2) of this section.

Part 314—New Drug Applications

5. In § 314.1, by revising paragraph (a) to read as follows:

§ 314.1 Applications.

(a)(1) Applications to be filed under section 505(b) of the act shall be submitted in the form described in paragraph (c) of this section and, if for human use, optionally in the form described in paragraph (d) of this section and assembled as required by paragraph (e) of this section; if the drug is intended for human use and is one for which an abbreviated new drug application has been found by the Food and Drug Administration to be sufficient, the application may be limited to the information described in paragraph (f) of this section unless otherwise specified in such finding. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part. Translations of literature printed in a foreign language shall be accompanied by copies of the original publication. The application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant or such authorized representative does not reside or have a place of business within the United States, the application must also furnish the name and post office address of, and must be countersigned by, an authorized attorney, agent, or official residing or main-

taining a place of business within the United States.

(2) Applications, including subsequent amendments and supplements for the products listed in paragraph (a) of this section shall be submitted to the Director, Bureau of Biologics, 8800 Rockville Pike, Bethesda, MD 20014 instead of to the address shown in paragraph (c) of this section. In reading this Part 314, applicants of such listed products should substitute "Bureau of Biologics" for "Bureau of Drugs" wherever it appears. The products are as follows:

(i) Ingredients packaged together with containers intended for the collection, processing, or storage of blood and blood components.

(ii) Urokinase products.

* * * * *

Pursuant to the Administrative Procedure Act (5 U.S.C. 553 (b) and (d)), the Commissioner finds that notice, public procedure, and delayed effective date are unnecessary for the promulgation of this order because it does not impose a duty or burden on any person, but merely provides notice of internal administrative designation of responsibility.

Effective date: This regulation is effective on November 23, 1976.

(Secs. 505, 701(a), 52 Stat. 1052-1053 as amended, 1055 (21 U.S.C. 355, 371(a)); sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262))

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34524 Filed 11-22-76;8:45 am]

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart B—Redelegations of Authority From the Commissioner of Food and Drugs

Grants and Service Fellowships

The Food and Drug Administration (FDA) is amending the regulation setting forth its delegation of authority concerning the awarding of service fellowships; effective November 23, 1976.

By memorandum dated May 24, 1976, the Executive Officer, Public Health Service (PHS), delegated to the Commissioner of Food and Drugs the authority to award service fellowships under section 207(g) of the Public Health Service Act (42 U.S.C. 209(g)). The delegation is effective upon approval of a Service Fellowship Program by an authorized PHS official. On July 27, 1976, the Director, Office of Administrative Management, PHS, approved the establishment of the FDA staff Fellowship Program. This amendment revises and corrects the Commissioner's delegation of service fellowship authority.

Further redelegation of the authority delegated by this amendment is not authorized. Authority delegated by this amendment to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis, unless prohibited by a restriction written into the document designating him as "acting," or unless it is not legally permissible.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 5 is amended by revising § 5.36 and adding new § 5.53 to read as follows:

§ 5.36 Delegations regarding grants.

(a) The Associate and Deputy Associate Commissioner for Science are authorized to approve or disapprove all applications for grants under secs. 301, 307, 311, and 356 of the Public Health Service Act, and to select officials to serve as program managers to exercise scientific oversight and to monitor grantee progress.

(b) The Associate and Deputy Associate Commissioner for Administration and the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Administration are authorized to execute grant awards upon approval by the Associate or Deputy Associate Commissioner for Science, and to notify grantees of officials who will serve as the Food and Drug Administration program manager for their grant.

§ 5.53 Delegations regarding service fellowships.

The Associate and Assistant Commissioners, the Directors of Bureaus, the Director, National Center for Toxicological Research, and the Executive Director of Regional Operations are authorized to designate persons to receive service fellowships in the Food and Drug Administration Staff Fellowship Program under sec. 207(g) of the Public Health Service Act.

Effective date: This amendment shall be effective on November 23, 1976.

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

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.76-34520 Filed 11-22-76;8:45 am]

[Docket No. 76C-0432]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of Ext. D&C Yellow No. 7 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics; effective on December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 26) for the "permanent" listing of Ext. D&C Yellow No. 7 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, D.C. 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, D.C. 20005); and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, D.C. 20006), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that Ext. D&C Yellow No. 7 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics under new §§ 8.4178 and 8.7258 (21 CFR 8.4178 and 8.7258). The provisional listing of Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics under § 8.501(c) (21 CFR 8.501(c)), which was etxended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list Ext. D&C Yellow No. 7 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (31 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. Ext. D&C Yellow No. 7 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (Ext. D&C)" under § 8.501(c).

This order establishes specifications for the certification of batches of Ext. D&C Yellow No. 7 that are more restrictive than those currently prescribed under § 9.307 (21 CFR 9.307). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specification currently prescribed in § 9.307 become obsolete upon the effective date of new §§ 8.4178 and 8.7258. However, it is necessary to maintain § 9.307 to provide for the use of the color additive in lakes. Accordingly,

§ 9.307 is revised to reference the identity nomenclature and specifications prescribed by § 8.4178.

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 (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (c) of § 8.501 Provisional lists of color additives, the entry for Ext. D&C Yellow No. 7 for use in externally applied drugs and cosmetics is deleted.

b. In Subpart E, new § 8.4178 is added to read as follows:

§ 8.4178 Ext. D&C Yellow No. 7.

(a) *Identity.* (1) The color additive Ext. D&C Yellow No. 7 is principally the disodium salt of 8-hydroxy-5,7-dinitro-2-naphthalenesulfonic acid.

(2) Color additive mixtures for drug use made with Ext. D&C Yellow No. 7 may contain only those diluents that are suitable and that are listed in Subpart F of this part as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* Ext. D&C Yellow No. 7 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 good manufacturing practice:

Sum of violatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.
Water-insoluble matter, not more than 0.2 percent.
1-Naphthol, not more than 0.2 percent.
2,4-Dinitro-1-naphthol, not more than 0.03 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85 percent.

(c) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used in externally applied drugs in amounts consistent with good manufacturing practice.

(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 § 8.32.

(e) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this Part.

3. In Subpart G, new § 8.7258 is added to read as follows:

§ 8.7258 Ext. D&C Yellow No. 7.

(a) *Identity and specifications.* The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4178(a) (1) and (b).

(b) *Uses and restrictions.* Ext. D&C Yellow No. 7 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of Ext. D&C Yellow No. 7 shall be certified in accordance with regulations in Subpart A of this Part.

4. Part 9 is amended by revising § 9.307 to read as follows:

§ 9.307 Ext. D&C Yellow No. 7.

The color additive Ext. D&C Yellow No. 7 shall conform in identity and specifications to the requirements of § 8.4178(a) (1) and (b) of this chapter. Ext. D&C Yellow No. 7 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 23, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, 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. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This order shall become effective on December 27, 1976, 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)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 USC. 376 note).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate,
Commissioner for Compliance.

[FR Doc.76-34518 Filed 11-22-76;8:45 am]

[Docket No. 76C-0425]

PART 8—COLOR ADDITIVES
PART 9—COLOR CERTIFICATION

Listing of D&C Red No. 34 for Use in Externally Applied Drugs and Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Red No. 34 for use in externally applied drugs and cosmetics; effective on December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 38) for the "permanent" listing of D&C Red No. 34 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry and Fragrance Association, 1133 15th St. NW., Washington, D.C. 20005); the Pharmaceutical Manufacturers Association (1155 15th St. NW., Washington, D.C. 20005), and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th St. NW., Washington, D.C. 20006), c/o Hazelton Laboratories, Inc., P.O. Box 30, Falls Church, Va. 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Red No. 34 is safe under the conditions set forth below for use in coloring externally applied drugs and cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Red No. 34 for use in externally applied drugs and cosmetics under new §§ 8.4128 and 8.7195 (21 CFR 8.4128 and 8.7195). The provisional listing of D&C Red No. 34 for use in externally applied drugs and cosmetics under § 8.501(b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing will continue until December 31, 1976 unless terminated or extended by regulation.

This order does not list D&C Red No. 34 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Red No. 34 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 8.501(b).

This order establishes specifications for the certification of batches of D&C Red

No. 34 that are more restrictive than those currently prescribed under § 9.179 (21 CFR 9.179). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specifications currently prescribed in § 9.179 become obsolete upon the effective date of new §§ 8.4128 and 8.7195. However, it is necessary to maintain § 9.179 to provide for the use of the color additive in lakes. Accordingly, § 9.179 is revised to reference the identity nomenclature and specifications prescribed by § 8.4128.

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), (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)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I of Title 21 of the Code of Federal Regulations are amended as follows:

1. Part 8 is amended:

§ 8.501 [Amended]

a. In paragraph (b) of § 8.501 Provisional lists of color additives, the entry for D&C Red No. 34 for use in externally applied drugs and cosmetics is deleted.

b. In subpart E, new § 8.4128 is added to read as follows:

§ 8.4128 D&C Red No. 34.

(a) *Identity.* (1) The color additive D&C Red No. 34 is principally the calcium salt of 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azol - 2 - naphthalenecarboxylic acid.

(2) Color additive mixtures for drug use made with D&C Red No. 34 may contain only those diluents that are suitable and that are listed in Subpart F of this Part as safe for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Red No. 34 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 good manufacturing practice:

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated at sodium salts), not more than 15 percent.
2-Amino-1-naphthalensulfonic acid, calcium salt, not more than 0.2 percent.
3-Hydroxy-2-naphthoic acid, not more than 0.4 percent.
Subsidiary colors, nor more than 4 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), nor more than 3 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 D&C Red No. 34 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

(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 § 8.32.

(e) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Subpart A of this Part.

c. In Subpart G, new § 8.7195 is added to read as follows:

§ 8.7195 D&C Red No. 34.

(a) *Identity and specifications.* The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 8.4128(a)(1) and (b).

(b) *Uses and restrictions.* D&C Red No. 34 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 8.32.

(d) *Certification.* All batches of D&C Red No. 34 shall be certified in accordance with regulations in Subpart A of this part.

2. Part 9 is amended by revising § 9.179 to read as follows:

§ 9.179 D&C Red No. 34.

The color additive D&C Red No. 34 shall conform in identity and specifications to the requirements of § 8.4128(a)(1) and (b) of this chapter. D&C Red No. 34 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing order may at any time on or before December 23, 1976, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 8.19 (21 CFR 8.19). If a hearing is requested, the objections shall state the issues for the hearing, 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. Five copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this order. Received objections may be seen in the above office during working hours, Monday through Friday.

Effective date: This order shall become effective December 27, 1976, 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)); Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note).)

Dated: November 17, 1976.

JOSEPH P. HILE,
Associate Commissioner for Compliance.

[FR Doc.78-34519 Filed 11-22-76;8:45 am]

[Docket No. 76C-0441]

PART 8—COLOR ADDITIVES

PART 9—COLOR CERTIFICATION

Listing of D&C Brown No. 1 for Use in Externally Applied Cosmetics

The Food and Drug Administration (FDA) is "permanently" listing D&C Brown No. 1 for use in externally applied cosmetics; effective December 27, 1976; objections on or before December 23, 1976.

A notice published in the FEDERAL REGISTER of August 6, 1973 (38 FR 21199) stated that a petition (CAP 8C0087) for the "permanent" listing of D&C Brown No. 1 as a color additive for use in externally applied cosmetics had been filed by the Cosmetic Toiletry and Fragrance Association (1133 15th St. NW., Washington, DC 20005), c/o Hazleton Laboratories, Inc., P.O. Box 30, Falls Church, VA 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner has evaluated the data in the petition and concludes that D&C Brown No. 1 is safe under the conditions set forth below for use in coloring externally applied cosmetics and that certification is necessary for the protection of the public health. This order "permanently" lists D&C Brown No. 1 for use in externally applied cosmetics under new § 8.7061 (21 CFR 8.7061). The provisional listing of D&C Brown No. 1 for use in externally applied cosmetics under § 8.501(b) (21 CFR 8.501(b)), which was extended to December 31, 1976 by regulation published in the FEDERAL REGISTER of September 23, 1976 (41 FR 41856), and the corresponding § 9.230 *D&C Brown No. 1* (21 CFR 9.230), which prescribes specifications for the color additive while provisionally listed, will be deleted when this order becomes effective on December 27, 1976, unless this order is stayed by the timely filing of objections, in which case the provisional listing and § 9.230 will continue in effect until December 31, 1976 unless terminated or extended by regulation.

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 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 (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Parts 8 and 9 of Chapter I