inserted in lieu of the statement of the terms of substance. If the proposed rule change amends an existing rule, indicate changes in the rule by brackets for words to be deleted and underlined for words to be added.)

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements. (Reproduce the headings, and summarize briefly the most significant aspects of the responses, to Items 3, 4, and 5 of Form 19b–4, redesignating them as A, B, and C, respectively.)

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

(If the proposed rule change is to be considered by the Commission pursuant to Section 19(b)(2) of the Act, the following paragraph should be used.)Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

(If the proposed rule change is to take, or to be put into, effect pursuant to Section 19(b)(3)(A) of the Act and paragraph (f)(6) of Rule 19b–4 thereunder, the following paragraph should be used.)

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

(If the proposed rule change is to take, or to be put into, effect pursuant to Section 19(b)(3)(A) of the Act and subparagraphs (1)–(5) of paragraph (f) of Rule 19b–4 thereunder, the following paragraph should be used.)

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and paragraph (f) of Rule 19b-4 thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

(If the proposed rule change is to be considered by the Commission pursuant to Section 19(b)(7)(D) of the Act, the following paragraph should be used.)

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) After consultation with the Commodity Futures Trading Commission, institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number XX on the subject line.

Paper Comments

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File Number XX. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the [exchange]. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number XX and should be submitted on or before [insert date 21 days from publication in the **Federal Register**].

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[1]

Secretary

[FR Doc. 04–22628 Filed 10–5–04; 9:06 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 1987C–0023]

Listing of Color Additives Subject to Certification; D&C Black No. 2; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 30, 2004, for the final rule that appeared in the **Federal Register** of July 28, 2004 (69 FR 44927). The final rule amended the color additive regulations to provide for the safe use of D&C Black No. 2 (a high purity furnace black, subject to FDA batch certification) as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

DATES: Effective date confirmed: August 30, 2004.

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3423.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 28, 2004 (69 FR 44927), FDA amended the color additive regulations to add § 74.2052 *D&C Black No. 2* (21 CFR 74.2052) to provide for the safe use of D&C Black No. 2 as a color additive in the following cosmetics: Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers and rouge, makeup and foundation, and nail enamel.

FDA gave interested persons until August 27, 2004, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore,

[1] 17 CFR 200.30–3(a)(12).

FDA finds that the effective date of the final rule that published in the **Federal Register** of July 28, 2004, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (1410.10 of the FDA Staff Manual Guide), notice is given that no objections or requests for a hearing were filed in response to the July 28, 2004, final rule. Accordingly, the amendments issued thereby became effective August 30, 2004.

Dated: September 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22605 Filed 10–7–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

New Animal Drugs; Flunixin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk.

DATES: This rule is effective October 8, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *joan.gotthardt@fda.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 101–479 that provides for the veterinary prescription use of BANAMINE (flunixin meglumine) Injectable Solution by intravenous injection in lactating dairy cattle for control of pyrexia associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. It also provides for the veterinary prescription use of flunixin meglumine solution by intravenous injection for control of pyrexia associated with acute bovine mastitis and for the establishment of a tolerance for residues of flunixin in milk. The supplemental NADA is approved as of August 19, 2004, and the regulations are amended in 21 CFR 522.970 and 556.286 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act the act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning August 19, 2004. The 3 years of marketing exclusivity applies only to the new indication of control of pyrexia associated with acute bovine mastitis.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.970 is amended by revising the section heading; by revising paragraph (b)(1); by redesignating paragraph (b)(2) as paragraph (b)(3); by adding new paragraph (b)(2); and by revising paragraphs (e)(2) introductory text, (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See No. 000061 for use as in paragraph (e) of this section.

(2) See Nos. 055529, 057561, and 059130 for use as in paragraphs (e)(1), (e)(2)(i)(A), (e)(2)(ii)(A), and (e)(2)(iii), of this section.

* * * * *

(e) * * *

* * * * *

(2) *Cattle*—(i) *Amount.* (A) 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day, as a single dose or divided into two doses administered at 12-hour intervals, intravenously, for up to 3 days.

(B) 2.2 mg/kg (1.0 mg/lb) of body weight given once by intravenous administration.

(ii) *Indications for use.* (A) For control of pyrexia associated with bovine respiratory disease and endotoxemia. Also indicated for control of inflammation in endotoxemia.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For No. 000061: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529, 057561, and 059130: Not for use in lactating or dry dairy cows.