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[Page 427-430]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 80_COLOR ADDITIVE CERTIFICATION--Table of Contents

Subpart B_Certification Procedures

Sec. 80.21 Request for certification.

A request for certification of a batch of color additive shall:

- (a) Be addressed to the Commissioner of Food and Drugs.
- (b) Be prepared in the manner set forth in paragraph (j) of this section.
- (c) Be submitted in duplicate.
- (d) Be signed by a responsible officer of the person requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.
- (e) Show the name and post office address of the actual manufacturer in

[[Page 428]]

case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in Sec. 80.10 unless the person has established with the Food and Drug Administration an advanced deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by Sec. 80.10 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in Sec. 80.22 consisting of:

- (1) Four ounces in the case of straight colors and lakes.
- (2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

- (1) The name of a straight color shall be the name of the color as

listed in parts 74 and 81 of this chapter.

(2) The name of a lake shall be the name derived in the manner described in part 82 of this chapter.

(3) The name of a mixture shall be the name given to such mixture by the person requesting certification.

(4) The name of a repack shall be the name described in paragraph (h)(1), (2), or (3) of this section, whichever is applicable.

(i) The information and samples enumerated in paragraphs (a) to (h), inclusive, of this section are the minimum required. Additional information and samples shall be submitted at the request of the Food and Drug Administration when such additional information and samples are necessary to determine compliance with the requirements of Sec. 80.31 for the issuance of a certificate.

(j) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack of a previously certified color additive, or a color additive mixture.

(1) Request for certification of a batch of straight color additive.

Date -----

Office of Cosmetics and Colors (HFS-100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color _____
(As listed in 21 CFR part 74)

Batch number _____
(Manufacturer's number)

Batch weighs ---- pounds
Batch manufactured by ----- at ----- (Name and
address of actual manufacturer)

How stored pending certification _____

(State conditions of storage, with kind and size of containers,
location, etc.)

Certification requested of this color for use in _____

(State proposed uses)

Required fee, \$---- (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) -----

By -----

(Title)

(2) Request for certification of a batch of color additive lake.

Date -----

Office of Cosmetics and Colors (HFS-100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color _____
Batch number _____
(Manufacturer's number)

Batch weighs ---- pounds

Name of color used _____

[[Page 429]]

Quantity ---- pounds

Lot number _____
(When certification of the lake
for use in foods is requested)

Precipitant used _____
Substratum used _____

Quantity ---- pounds
Batch manufactured by ----- at ----- (Name and address of
actual manufacturer)

How stored pending certification _____

(State conditions of storage, with kind and size of containers,
location, etc.)
Certification requested of this color for use in _____

(State proposed uses)

Required fee, \$---- (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) -----
By -----

(Title)

(3) Request for certification of a repack of a batch of certified color additive.

Date -----

Office of Cosmetics and Colors (HFS-100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color _____
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number _____
Certified color content _____
This color obtained from _____
Batch number _____

Batch weighs ---- pounds

How stored pending certification _____

(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested for use in _____

(State proposed uses)

Required fee, \$---- (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) -----
By -----

(Title)

(4) Request for certification of a batch of color additive mixture.

Date -----

Office of Cosmetics and Colors (HFS-100),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
5100 Paint Branch Pkwy.,
College Park, MD 20740

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____

(Manufacturer's trade name)

Batch number _____
(Manufacturer's number)

Weight of batch ---- pounds
Volume of batch ---- (If liquid) gallons

Batch manufactured by _____

Constituents of the mixture:

1. Color(s). (List separately each color and each lot number.)

Name of color
as certified Lot number

Quantity used
(in pounds) Obtained from

2. List of diluents. (List separately each diluent.)

Name of diluent

Quantity used

By volume
By weight (if liquid)

Batch mixed as follows _____
(Describe in detail)

How stored pending certification _____

(State conditions of storage, with kind and size of containers,
location, etc.)

Certification requested for use in _____

[[Page 430]]

(State proposed uses)

Required fee, \$---- (drawn to the order of Food and Drug
Administration).

The accompanying sample was taken after the batch was mixed in
accordance with 21 CFR 80.22 and is accurately representative thereof.

(Signed) -----
By -----

(Title)

[42 FR 15662, Mar. 22, 1977; 44 FR 17658, Mar. 23, 1979; 44 FR 22053, Apr. 13, 1979, as amended at 54 FR 24890, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]