

§ 80.22

21 CFR Ch. I (4-1-04 Edition)

(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]

§ 80.22 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

- (a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.
- (b) Held under the control of the person requesting certification until certified.
- (c) Be labeled to show:
 - (1) The name of the color additive.
 - (2) The manufacturer's batch number.
 - (3) The quantity of such batch.
 - (4) The name and post-office address of the person requesting certification of such batch.
- (5) Be accompanied by any label or labeling intended to be used.

§ 80.31 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

- (1) A request submitted in accordance with § 80.21 appears to contain no untrue statement of a material fact;
- (2) Such color additive conforms to the specifications and any other conditions set forth therefor in parts 81 and 82 of this chapter.
- (3) The batch covered by such request otherwise appears to comply with the regulations in this chapter, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by part 74, 81, and 82 of this chapter, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 80.21, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal. Any person who contests such refusal shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

§ 80.32 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color additive is received by the person to whom it is issued, any such color additive becomes changed in composition, such certificates shall not be effective with respect to such changed color additive and such changed color additive shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(c) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color additive. After such expiration, such color additive shall be considered to be from a batch that has not been certified in accordance with this part; except that such color additive shall not be so considered when