

PART 276—INTERPRETATIVE RELEASES RELATING TO THE INVESTMENT ADVISERS ACT OF 1940 AND GENERAL RULES AND REGULATIONS THEREUNDER

4. Part 276 is amended by adding Release No. 1A-1710 and the release date of March 23, 1998, to the list of interpretative releases.

By the Commission.

Dated: March 23, 1998.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98-8001 Filed 3-26-98; 8:45 am]

BILLING CODE 8010-01-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 239 and 274

[Release Nos. 33-7512A; 34-39748A; IC-23064A; File No. S7-10-97]

RIN 3235-AE46

Registration Form Used by Open-End Management Investment Companies; Correction

AGENCY: Securities and Exchange Commission.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations which were published in the **Federal Register** on Monday, March 23, 1998 (63 FR 13916). The regulations adopted amendments to Form N-1A, the form used by mutual funds to register under the Investment Company Act of 1940 and to offer their shares under the Securities Act of 1933.

DATES: Effective on June 1, 1998.

FOR FURTHER INFORMATION CONTACT: Doretha M. VanSlyke, Attorney, 202-942-0721.

SUPPLEMENTARY INFORMATION: As published, the final regulations did not contain the Office of Management and Budget approval information that needs to appear on the front page of Form N-1A.

Accordingly, the publication on March 23, 1998 of the final regulations which were the subject of FR Doc. 98-7070 is corrected as follows.

On page 13944, first column, in Form N-1A, the Office of Management and Budget approval information is corrected as follows:

“OMB Approval

OMB Number: 3235-0307.

Expires: 05/31/00.

Estimated average burden hours per response: 212.95”.

Dated: March 23, 1998.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98-8035 Filed 3-26-98; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 93C-0248]

Listing of Color Additives Exempt from Certification; Canthaxanthin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of canthaxanthin as a color additive in the feed of salmonid fish to enhance the color of their flesh. This action is in response to a petition filed by BASF Corp.

DATES: Effective April 28, 1998, except as to any provisions that may be stayed by the filing of proper objections; written objections and request for a hearing by April 27, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3078.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of August 12, 1993 (58 FR 42975), FDA announced that a color additive petition (CAP 3C0240) had been filed by BASF Corp., 100 Cherry Hill Rd., Parsippany, NJ 07054. The petitioner requested that FDA amend the color additive regulations to provide for the safe use of canthaxanthin as a color additive in the feed of salmonid fish. The petition was filed under section 721(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e(d)).

II. Safety Evaluation

Canthaxanthin (β,β -carotene-4,4'-dione) and astaxanthin are two coloring substances found in wild salmonids

(Refs. 1 and 2). They are responsible for imparting the pink or red coloring to these fish. Astaxanthin, found in crustaceans that constitute a significant portion of the diet of wild salmonids, is the primary coloring substances found in wild salmonids (Ref. 2).

Canthaxanthin contributes less coloring to wild salmonids and is present at levels of 0.3 to 1.0 milligram per kilogram (mg/kg) (Ref. 1). Coloration of aquacultured salmonids that is comparable to that in wild salmonids may be achieved by feeding aquacultured salmonids a diet that is higher in canthaxanthin than is present in the diet of wild fish.

Based on the data and information that is before the agency, FDA has determined that the use of canthaxanthin in fish feed at a level of 80 mg/kg (72 grams (g)/ton) is safe. This level will result in 4 to 8 mg/kg of the color additive in the flesh of salmonids (Ref. 3).

As part of its safety evaluation, FDA estimated the cumulative exposure to canthaxanthin. The cumulative exposure consists of exposure from the proposed use in salmonids and the exposure from all currently listed uses. FDA used data and information contained in the petition concerning residues of canthaxanthin in salmonids to estimate the exposure to canthaxanthin from the proposed use. The agency used these data and information, in addition to data and information on the currently regulated uses of canthaxanthin, to determine the cumulative exposure to canthaxanthin.

FDA estimates that, for the petitioned use, a level of 8 mg of canthaxanthin/kg salmonid flesh will result in an exposure of no greater than 0.08 mg/person/day (mg/p/d) for an individual consuming those fish at the 90th percentile (Ref. 4). To estimate, for this final rule, the exposure to canthaxanthin from all currently regulated uses, FDA used the poundages of canthaxanthin used in food taken from the 1982 and 1987 National Academy of Sciences' (NAS) surveys of additives used in food (Ref. 5).

FDA previously estimated the exposure to canthaxanthin from currently regulated uses, when, in 1985, FDA issued a regulation that allowed the use of canthaxanthin in broiler chicken feed for coloring skin (hereinafter referred to as “the 1985 rule”) (50 FR 47532, November 19, 1985). As part of its review of the BASF Corp. petition, FDA evaluated the exposure to canthaxanthin, based on currently regulated uses, and found that the calculation done for the 1985 rule was erroneous in that it overestimated

exposure to the color additive. The preamble to the 1985 rule contained a theoretical estimate of exposure to canthaxanthin based on use of the color additive in all food. This worst case estimate for exposure to canthaxanthin was determined to be 100 mg/p/d (Ref. 6). The estimated exposure to canthaxanthin from its use in chicken feed (6 mg/p/d) was then added to the 100 mg/p/d, resulting in a cumulative estimated exposure of 106 mg/p/d.

FDA has now determined that the 100 mg/p/d estimate is unreasonably exaggerated because for technologic and aesthetic reasons canthaxanthin will not be used to color all foods. FDA has also determined that it is incorrect to add the 6 mg/p/d estimate of exposure from its use in chicken feed to the 100 mg/p/d worst case estimate because the worst case estimate already included the intake of colored chicken. Furthermore, FDA has determined that the 6 mg/p/d estimate of exposure from colored chicken skin is unreasonably exaggerated because it would require a daily intake of approximately 12,000 g (approximately 264 pounds) of chicken containing canthaxanthin at 50 part per billion (ppb) to achieve this exposure to canthaxanthin. Consequently, FDA recalculated the exposure to canthaxanthin from use in chicken feed, and used the recalculated exposure level in order to determine the exposure from all currently regulated uses of the color additive. FDA then added the exposure from the proposed use of canthaxanthin in salmonids to the exposure from the currently regulated uses to estimate the cumulative exposure to canthaxanthin.

The use of canthaxanthin in feed results in a residual level of canthaxanthin of 50 ppb in chicken meat, of 150 ppb in chicken fat, and of 2 parts per million in chicken livers. Combining these data with intakes of these foods gives an exposure to canthaxanthin from its use in chicken feed of 0.007 mg/p/d (Ref. 7). FDA determined, based on the 1982 and 1987 NAS surveys, that the per capita disappearance of canthaxanthin was 0.027 mg/p/d (1982 data) and 0.008 mg/p/d (1987 data). To provide a conservative, yet reasonable estimate of exposure using these poundage data, FDA assumed that only 10 percent of the population consumes the entire output of food colored with canthaxanthin and chose the higher of the two per capita disappearances (the 1982 data) to calculate a per capita exposure of 0.27 mg/p/d (0.027 mg/p/d \times 10 = 0.27 mg/p/d) from all pre-1985 uses of the color additive. Adding the recalculated exposure from use in

chicken feed (0.007 mg/p/d) to the exposure from currently regulated uses based upon the 1982 estimate of 0.27 mg/p/d results in a total exposure from currently regulated uses of 0.28 mg/p/d. Therefore, the cumulative exposure to canthaxanthin from its currently regulated uses plus the petitioned use is 0.36 mg/p/d (0.28 mg/p/d current use + 0.08 mg/p/d proposed use in salmonids).

Because of the numerous conservative assumptions used in calculating exposure, the actual cumulative exposure from the current and petitioned uses of canthaxanthin is likely to be substantially less than the estimated cumulative exposure of 0.36 mg/p/d.

The acceptable daily intake (ADI) of canthaxanthin, as previously determined by FDA, is 150 mg/p/d (50 FR 47532 at 47533). FDA's estimates for the 90th percentile human exposure to canthaxanthin in aquacultured fish flesh of 0.08 mg/p/d and the cumulative exposure for canthaxanthin of 0.36 mg/p/d represent only small fractions of this amount.

In 1996, the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization and the World Health Organization (WHO) determined an ADI of 0.03 mg/kg body weight (bw) (1.8 mg/p/d) for canthaxanthin based on a no-observed-effect-level of 0.25 mg/kg bw/d in humans and a safety factor of 10 (Ref. 8). JECFA's ADI was based on consideration of recent reports of crystalline retinopathy in subjects consuming large quantities of canthaxanthin as part of tanning pills and animal studies conducted to study this retinal effect.

FDA has proceeded to make a determination on the petitioned use of canthaxanthin even though it has yet to evaluate the studies that JECFA considered in determining JECFA's 1996 ADI. FDA believes it is entirely sound to do so because the exposure from the petitioned use of canthaxanthin is well below both FDA's and JECFA's ADI (Ref. 9). Nevertheless, the agency may determine, in response to a petition for an additional use of canthaxanthin, that a reevaluation of the exposure to this color additive is warranted, including consideration of the studies that JECFA considered in arriving at its 1996 ADI.

The agency has reviewed the safety information for canthaxanthin and finds that there is no basis for concern that harm will result to consumers from the current and petitioned uses of canthaxanthin. Thus, FDA concludes that there is a reasonable certainty of no

harm from the current and petitioned uses of canthaxanthin (Ref. 10).

FDA received one comment on the petition. This comment endorsed the petitioned use of canthaxanthin.

III. Stability

FDA finds that canthaxanthin is relatively unstable. Pure crystalline canthaxanthin must be stored in the absence of light, heat, and oxygen to minimize chemical changes and decomposition that would result in loss of color (Refs. 1 and 11). Thus, it is necessary to produce a stabilized form of canthaxanthin for it to be marketed for addition to salmonid feed for the purpose of coloring fish flesh. Because of this concern, the petitioner manufactures canthaxanthin in a beadlet form, which the manufacturer has shown provides increased stability to the color additive mixture. Therefore, newly added § 73.75(c)(3)(i) (21 CFR 73.75(c)(3)(i)) requires that canthaxanthin be added to fish feed only in the form of a stabilized color additive mixture.

IV. Labeling Requirements

All color additives, in accordance with § 70.25 (21 CFR 70.25), require sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by the agency in other applicable regulations. Therefore, the labeling of the color additive, canthaxanthin, and any mixture prepared therefrom, is subject to the requirements of § 70.25.

According to § 70.25(a)(4), an expiration date for a color additive must be stated on its label if stability data require it. FDA finds that because of the instability of canthaxanthin, an expiration date must be stated on the label of sealed and open containers, in accordance with § 70.25(a)(4). FDA also finds that declaration of the expiration date constitutes a material fact that must be disclosed on the label of the color additive mixture under sections 201(n) and 403(a)(1) of the act (21 U.S.C. 321(n) and 343(a)(1)) because failure to do so would constitute a failure to reveal facts material in light of the other representations made on the label and material with respect to consequences which may result from the use of the color additive. The use of canthaxanthin requires the declaration of expiration dates because this relatively unstable color additive can decompose to products that would not be coloring agents and thus would not affect the color of salmonid flesh.

In addition to the requirements for labeling the color additive or color

additive mixture, the ingredient list on fish feed, to which canthaxanthin is added, must identify the presence of the color additive under § 501.4 (21 CFR 501.4). New § 73.75(d)(3) references § 501.4 to ensure that the presence of canthaxanthin as a color additive in the fish feed will be declared on the ingredient label.

Finally, the presence of the color additive must be declared on the label of any food, including salmonid fish, containing added canthaxanthin and food containing such salmonid fish as an ingredient. Section 101.22(b) (21 CFR 101.22(b)) requires a food that bears or contains artificial coloring, such as salmon artificially colored with canthaxanthin, to bear labeling even though such food is not in package form. Section 101.22(c) requires that label statements of artificial coloring be "likely to be read by the ordinary person under customary conditions of purchase and use of such food."

Furthermore, § 101.22(k)(2) requires, in the statement of ingredients for a food to which any coloring has been added, and for which the coloring is not subject to certification, a declaration that makes it clear that a color additive has been used in the food. In addition, the presence of a color additive must be declared on any bulk container of food containing a color additive that is held at a retail establishment under the provisions in § 101.100(a)(2) (21 CFR 101.100(a)(2)). The ingredient label would prevent economic fraud in salmonid fish containing added canthaxanthin because the ingredient label would notify the consumer that the fish is artificially colored. Without such ingredient labeling, food comprising salmonid fish with added canthaxanthin would be deemed to be misbranded under section 403(k) of the act which states that: "A food shall be deemed to be misbranded * * * If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact * * *."

Therefore, in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2), labeling on any salmonid fish containing canthaxanthin is required to declare the presence of the color additive or color additive mixture. New § 73.75(d)(4) references §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) to ensure that, at the retail level, the presence of canthaxanthin as a color additive in the fish will be declared, and that the labeling of the bulk fish container, including a list of ingredients, will be displayed on the container or on a counter card with similar information.

V. Conclusions

FDA has evaluated the data in the petition and other relevant material and concludes that canthaxanthin is safe and suitable for the intended use, and therefore, that the regulations in § 73.75 should be amended as set forth below. In addition, based upon the factors listed in 21 CFR 71.20(b), the agency concludes that certification of canthaxanthin is not necessary for the protection of the public health.

Because of the relative instability of crystalline canthaxanthin, the agency believes that the use of this color additive should be in the form of a stabilized color additive mixture for all regulated uses of canthaxanthin. In addition, the agency believes that stability data for canthaxanthin require that the labeling of this color additive for all regulated uses include an expiration date. Therefore, the agency is requiring, in new § 73.75(c) and (d), that the use of canthaxanthin in fish feed be in the form of a stabilized color additive mixture and that the labeling include an expiration date. The currently listed uses for canthaxanthin have no such requirements. Therefore, the agency plans to publish a proposed rule to amend the current regulation in § 73.75 to require, for such uses, that canthaxanthin be in the form of a stabilized color additive mixture and that the labeling include an expiration date (Ref. 12).

VI. Inspection of Documents

In accordance with § 71.15(a) (21 CFR 71.15(a)), 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 (address above) by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before April 27, 1998, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

IX. 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. Christophersen, A. G., P. Knuthsen, and L. H. Skibsted, "Determination of Carotenoids in Salmonids," *Zeitschrift für Lebensmittel-Untersuchung Forschung*, 188:413-418, 1989.
2. Schiedt, K., F. J. Leuenberger, and M. Vecchi, "Natural Occurrence of Enantiomeric and Meso-Astaxanthin," *Helvetica Chimica Acta*, 64:449-457, 1981.
3. Storebakken, T., P. Foss, K. Schiedt, E. Austreng, S. Liaaen-Jensen, and U. Mainz, "Carotenoids in Diets for Salmonids IV. Pigmentation of Atlantic Salmon with Astaxanthin, Astaxanthin Dipalmitate and Canthaxanthin," *Aquaculture*, 65: 279-292, 1987.
4. Memorandum from M. DiNovi, FDA, to J. Wallwork, FDA, May 17, 1996.
5. National Academy of Sciences, "1987 Poundage and Technical Effects Update of Substances Added to Food," p. 98, Washington, DC, 1989.
6. Memorandum from L. Borodinsky, FDA, to J. Taylor, FDA, April 28, 1989.

7. Memorandum from M. DiNovi, FDA, to J. Wallwork, FDA, August 29, 1996.

8. Olsen, P. "Canthaxanthin," in *Toxicological Evaluation of Certain Food Additives and Contaminants in Food*. WHO Food Additive Series: 35, World Health Organization, Geneva, pp. 157-171, 1996.

9. Memorandum of April 17, 1997, FDA Meeting Regarding Canthaxanthin: JECFA's 1996 ADI.

10. Memorandum from C. Johnson, FDA, to J. Wallwork, FDA, September 10, 1996.

11. Bunnell, R. H., and B. Borenstein, "Canthaxanthin, A Potential New Food Color," *Food Technology*, 21: 13A-16A, 1967.

12. Memorandum of Telephone Conversation between J. Wallwork, FDA, and S. Turujman, FDA, July 8, 1996.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 73.75 is amended in paragraph (c)(1)(i) by removing the period at the end and by adding "; and" in its place, by adding paragraph (c)(3), and by revising paragraph (d) to read as follows:

§ 73.75 Canthaxanthin.

* * * * *

(c) * * *

(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;

(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and

(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(2) For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear

expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c)(3) of this section.

(3) The presence of the color additive in finished fish feed prepared according to paragraph (c)(3) of this section shall be declared in accordance with § 501.4 of this chapter.

(4) The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with §§ 101.22(b), (c), and (k)(2), and 101.100(a)(2) of this chapter.

* * * * *

Dated: March 19, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-8127 Filed 3-26-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 104, and 135

Foods and Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to correct certain errors that have become incorporated into the food labeling regulations. This action is being taken to improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: March 27, 1998

FOR FURTHER INFORMATION CONTACT: Theresa L. Thomas, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION: FDA has discovered that certain errors have become incorporated into the agency's codified regulations on food labeling. FDA is correcting these nonsubstantive errors.

In the **Federal Register** of June 3, 1996 (61 FR 27771), FDA published a final rule entitled "Revocation of Certain Regulations Affecting Food." The final rule, among other things, revoked

§ 100.130 (21 CFR 100.130). However, in issuing the rule, the agency inadvertently neglected to remove the cross-reference to § 100.130 in § 101.2. Also in the **Federal Register** of January 6, 1993 (58 FR 2079), FDA published a final rule entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label." The 1993 final rule, among other things, revised § 101.9 (21 CFR 101.9) in its entirety. However, in issuing the 1993 final rule, the agency inadvertently neglected to revise the reference to "§ 101.9(e)" that appeared in §§ 101.12 and 104.5 (21 CFR 101.12 and 104.5) to read "§ 101.9(g)." In this order, FDA is amending §§ 101.2, 101.12, and 104.5 to correct these inadvertent omissions.

In addition to these modifications, FDA is making a number of other minor corrections involving spelling and punctuation errors.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Lists of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 104, and 135 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

§ 101.2 [Amended]

2. Section 101.2 *Information panel of package form food* is amended by removing paragraph (c)(1)(ii)(B)(3)(i) and by redesignating paragraphs (c)(1)(ii)(B)(3)(ii), (c)(1)(ii)(B)(3)(iii), and (c)(1)(ii)(B)(3)(iv) as paragraphs (c)(1)(ii)(B)(3)(i), (c)(1)(ii)(B)(3)(ii), and (c)(1)(ii)(B)(3)(iii), respectively.