FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8220, FAX: 301–847–8640, or *Michael.Ortwerth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Antiviral Drugs Advisory Committee was established on October 7, 1980 (see 45 FR 79025, November 28, 1980). The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of acquired immune deficiency syndrome, human immunodeficiency virus related illnesses, and other viral, fungal and mycobacterial infections. The Committee is no longer needed and was terminated on February 15, 2015.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Antiviral Drugs Advisory Committee from the list of standing advisory committees in § 14.100 (21 CFR 14.100).

Therefore, the Agency is amending § 14.100(c) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155; Pub. L. 113–54.

§ 14.100 [Amended]

■ 2. Section 14.100 is amended by removing paragraph (c)(3) and redesignating paragraphs (c)(4) through (18) as paragraphs (c)(3) through (17).

Dated: March 16, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–06425 Filed 3–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2013–C–1008]

Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the expanded safe use of synthetic iron oxide as a color additive to include use in soft and hard candy, mints, and chewing gum. This action is in response to a petition filed by Wm. Wrigley Jr. Company (Wrigley).

DATES: This rule is effective April 21, 2015. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by April 20, 2015.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2013–C–1008, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2013–C–1008 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1275.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** of September 17, 2013 (78 FR 57105), we announced that we had filed a color additive petition (CAP 3C0298) submitted by Wm. Wrigley Jr. Company, c/o Exponent Inc., 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036 (petitioner). The petition proposed to amend the color additive regulations in § 73.200 *Synthetic Iron Oxide* (21 CFR 73.200) by expanding the safe use of synthetic iron oxide as a color additive to include use in soft and hard candy, mints, and chewing gum. The petitioner requested that the proposed uses be permitted at levels consistent with current good manufacturing practice (GMP). The petition also proposed to lower the specification limit for lead in synthetic iron oxide for human food use from 10 milligrams per kilogram (mg/kg; 10 parts per million (ppm)) to 5 mg/kg (5 ppm).

II. Background

Currently, synthetic iron oxides and their hydrated forms are approved as color additives for the following direct uses in human food, drugs, and cosmetics: (1) In sausage casings intended for consumption in an amount not exceeding 0.10 percent by weight of the finished food (§ 73.200); (2) in ingested or topically-applied drugs with a limit for ingested drugs of 5 milligrams, calculated as elemental iron, per day for labeled or prescribed dosages (21 CFR 73.1200); and (3) in cosmetics generally, including cosmetics applied to the area of the eye, in amounts consistent with GMP (21 CFR 73.2250).

Synthetically prepared iron oxides and their hydrated forms include red iron oxide, yellow iron oxide, black iron oxide, and brown iron oxide, which is

a blend of various iron oxides. For the subject petition, synthetic iron oxides are intended to be used in soft and hard candy, mints, and chewing gum in amounts consistent with GMP. The maximum GMP use level for iron oxides depends on the color of the iron oxide and the application. We have determined that the amount of the color additive used in these foods is self-limiting (Ref. 1). Therefore, there is no need for a specific upper limit on the percent by weight of iron oxide in hard and soft candies, mints, and chewing gum in the regulation for these foods.

III. Evaluation of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless the data and information available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations in 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive. To establish with reasonable certainty that a color additive intended for use in food is not harmful under its intended conditions of use, we consider the estimated human dietary exposure to the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all sources to an acceptable daily intake (ADI) established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. We typically use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic dietary exposure.

IV. Safety of Petitioned Use of the Additive

To support the safety of the proposed uses of synthetic iron oxide, Wrigley provided information about iron intake expected to result from the proposed new uses of synthetic iron oxide, as well as intake from other sources of iron. There are many dietary sources of iron, including from food ingredients, dietary supplements, and from food that contains naturally occurring iron. Specifically, Wrigley submitted detailed exposure estimates of iron that took into account the following: (1) The proposed uses of synthetic iron oxide as a color additive in soft and hard candy, mints, and chewing gum based on the maximum anticipated use levels; (2) the current use of synthetic iron oxide to color sausage casings; (3) background iron from conventional food based on the iron content declared on food labels; (4) iron from dietary supplements; and (5) oral exposure to iron oxides from their use as color additives in lipstick. These exposure estimates assumed that all of the iron that is present is absorbed in the gastrointestinal tract. Wrigley also provided exposure estimates to iron that took into account the bioavailability of iron from all current dietary sources, proposed uses, and lipstick. Wrigley compared these intake estimates to the Tolerable Upper Intake Level (UL) for iron established by the Institute of Medicine (IOM) of the National Academies. Based on this and other information, Wrigley concluded that the proposed use of synthetic iron oxide to color soft and hard candy, mints, and chewing gum is safe.

A. Estimated Daily Intake of Iron

Using food consumption data from the 2003–2008 National Health and Nutrition Examination Survey (NHANES), Wrigley's estimated exposure to iron from the proposed uses in soft and hard candy, mints and chewing gum for the U.S. population (2 years of age and older) to be 16.3 mg/p/day (d) for the 90th percentile consumer. Wrigley also provided dietary exposure estimates to iron for children 2 to 5 years of age, children 2 to 13 years of age, and adolescents and adults 14 years of age and older. For these population groups, Wrigley estimated the exposure to iron from the proposed uses at the 90th percentile to be 12.2 mg/p/d, 15.6 mg/p/d, and 16.4 mg/p/d, respectively. Wrigley also estimated the cumulative exposure to iron from all food sources (current and proposed) for the U.S. population (2 years of age and older) to be 40.6 mg/p/d for the 90th percentile consumer. Wrigley also provided dietary exposure estimates to iron for children 2 to 5 years of age, children 2 to 13 years of age, and adolescents and adults 14 years of age and older. For these population groups, Wrigley estimated the exposure to iron at the 90th percentile to be 31.2 mg/p/d, 34.6 mg/p/d, and 41.5 mg/p/d, respectively. In addition, Wrigley estimated exposure to iron from all food sources (current and proposed) and lipstick for females 10 to 13 years old, and 14 years of age and older. The exposure at the 90th percentile for these two population groups was 33.8 mg/p/d and 40.2 mg/p/d, respectively. Wrigley noted that these exposure estimates are conservative and assume that all of the iron present is bioavailable. We have no further questions regarding Wrigley's exposure estimates for iron in food and cosmetics and conclude that the petitioner's exposure estimates are sufficiently conservative to account for the use of iron oxides in ingested drugs (Ref. 2). We also conclude that exposure from indirect uses of iron oxides, such as for colorants for food-contact polymers authorized in 21 CFR 178.3297, would not significantly contribute to the overall exposure to iron oxides.

To address the bioavailability of iron, Wrigley provided information showing approximately 18 percent of iron from conventional foods and dietary supplements is bioavailable, and that about 1 percent of iron from synthetic iron oxide is bioavailable. Based on this information, Wrigley provided exposure estimates that take into account the bioavailability of iron. Wrigley estimated the exposure to bioavailable iron from the proposed uses at the 90th percentile to be 0.16 mg/p/d, 0.12 mg/p/d, 0.16 mg/p/d, and 0.16 mg/p/d for the U.S. population (2 years of age and older), children 2 to 5 years of age, children 2 to 13 years of age, and adolescents and adults 14 years of age and older, respectively. Wrigley estimated the cumulative exposure to bioavailable iron from all food sources (current and proposed) at the 90th percentile to be 6.02 mg/p/d, 4.68 mg/p/d, 4.99 mg/p/d, and 6.21 mg/p/d for the U.S. population (2 years of age and older), children 2 to 5 years of age, children 2 to 13 years of age, and adolescents and adults 14 years of age and older, respectively. For females 10 to 13 years old, and 14 years of age and older, Wrigley estimated exposure to bioavailable iron from all food sources (current and proposed) and lipstick to be 5.07 mg/p/d and 6.12 mg/p/d, respectively (Ref. 2).

B. Acceptable Intake Level for Iron

In 2000, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board at the IOM conducted an extensive review of relevant published scientific literature to determine dietary reference intakes and ULs for iron. The IOM published a detailed report that included a UL for iron of 40 mg/d for children (2 to 5 years of age and 2 to 13 years of age), and a UL of 45 mg/d for adolescents and adults (14 years of age and older) (Ref. 3).

The IOM considers the UL as the highest daily intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over

long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients and, generally speaking, may consider intake from such sources as food, water, nutrient supplements, and pharmacological agents. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and an uncertainty factor. We considered the ULs established by the IOM relative to the intake estimates as the primary basis for assessing the safety of iron from the proposed uses of synthetic iron oxide. We also reviewed scientific articles on the safety of iron submitted by Wrigley, as well as other relevant published studies available to FDA.

The exposure estimates to iron from all food sources, including the proposed use of synthetic iron oxide in soft and hard candy, mints, and chewing gum, at the 90th percentile for children 2 to 5 years of age and for children 2 to 13 years of age, without taking into account the bioavailability of the iron, is 31.2 mg/p/d and 34.6 mg/p/d, respectively. Both of these exposure estimates are below the UL for these age groups. The exposure estimate to iron from all food sources (current and proposed) and lipstick for females 10 to 13 years old at the 90th percentile of 33.8 mg/p/d is also below the UL established for this group. For adolescents and adults 14 years of age and older, the exposure estimate for iron at the 90th percentile of 41.5 mg/p/d is below the UL of 45 mg/p/d for adolescents 14 to 18 years of age. Similarly, the exposure estimate to iron from all food sources and lipstick for females 14 years of age and older of 40.2 mg/p/d at the 90th percentile is below the UL of 45 mg/p/d for adolescents and adults (14 years of age and older). Because the EDI of iron from all current and proposed food sources at the 90th percentile for each population group, which was estimated using conservative assumptions, is below the corresponding IOM UL for that population group, even without taking into account the low bioavailability of the iron from the petitioned uses, we conclude that there is a reasonable certainty of no harm from the proposed use of synthetic iron oxide as a color additive in soft and hard candy, mints, and chewing gum (Ref. 4).

C. Lead Specification

As discussed in section I, the petitioner proposed to lower the specification limit for lead in synthetic iron oxide for human food use in 21 CFR 73.200 from 10 mg/kg to 5 mg/kg. To support the lower lead specification, the petitioner submitted data on lead levels from batch analyses of synthetic iron oxide. The data demonstrates that the proposed lead limit of 5 ppm is achievable with the use of good manufacturing practices in the production of the color additive (Ref. 5). Because the lower specification limit is achievable, and also because the lower specification limit is consistent with the safe use of the color additive, we are lowering the lead specification limit for lead in synthetic iron oxide for human food as proposed. The lower specification applies to both the petitioned new use of synthetic iron oxide to color candy, chewing gum, and mints, as well as to the already-approved use of synthetic iron oxide for human food use in the coloring of sausage casings.

V. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of synthetic iron oxide in soft and hard candy, mints, and chewing gum is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned use. Consequently, we are amending the color additive regulations in 21 CFR part 73 as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we conclude that batch certification of synthetic iron oxide is not necessary for the protection of public health.

VI. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VII. Environmental Impact

We previously considered the environmental effects of this rule as stated in the September 17, 2013, notice of filing for CAP 3C0298 (78 FR 57105). We stated that we had determined, under 21 CFR 25.32(k), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Section 301(*ll*) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*)). Section 301(*ll*) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(*ll*)(1) to (*ll*)(4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(*ll*) of the FD&C Act or any of its exemptions apply to food products containing this color additive. Accordingly, this final rule should not be construed to be a statement that a product containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(*ll*) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(*ll*) of the FD&C Act applies.

X. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision to which you object and the grounds for your objection. Within each numbered objection, you must

specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

1. Memorandum to the File from A. Zajac, Division of Petition Review, February 27, 2015.
2. Memorandum from D. Doell, Chemistry Review Group, Division of Petition Review, to L. Dye, Regulatory Group II, Division of Petition Review, June 20, 2014.
3. Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington, DC: The National Academies Press, 2001.
4. Memorandum from S. Thurmond, Toxicology Team, Division of Petition Review, to L. Dye, Regulatory Group II, Division of Petition Review, September 9, 2014.
5. Memorandum from N. Hepp, Color Technology Team, Office of Cosmetics and Colors, to L. Dye, Division of Petition Review, September 23, 2013.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, and Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 73.200 is amended by revising paragraphs (b)(1) and (c)(1) to read as follows:

§ 73.200 Synthetic iron oxide.

* * * * *

(b) * * *

(1) Synthetic iron oxide for human food use shall conform to the following specifications:

Arsenic (as As), not more than 3 milligrams per kilogram (mg/kg) (3 parts per million (ppm)).

Lead (as Pb), not more than 5 mg/kg (5 ppm).

Mercury (as Hg), not more than 1 mg/kg (1 ppm).

* * * * *

(c) * * *

(1) Synthetic iron oxide may be safely used for human food use subject to the following restrictions:

(i) In sausage casings intended for human consumption in an amount not exceeding 0.10 percent by weight of the finished food.

(ii) In soft and hard candy, mints, and chewing gum at levels consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of the added color is authorized by such standards.

* * * * *

Dated: March 17, 2015.

Susan M. Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2015–06418 Filed 3–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–406]

Substances Temporarily Controlled Under Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule; technical amendments.

SUMMARY: This final rule makes technical and conforming amendments to the Drug Enforcement Administration regulations listing substances temporarily controlled under schedule I of the Controlled Substances Act. This final rule eliminates references to 7 substances that were previously subject to temporary control, but which have since been permanently controlled under schedule I, and redesignates 23 other substances that are currently temporarily controlled under schedule I. This action makes no substantive changes to the affected regulation.

DATES: This rule is effective March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.