the patent holder to assist the recipient of the exclusive patent rights in developing and commercializing the product covered by the patent. These co-rights include, but are not limited to, co-development, co-promotion, co-marketing and co-commercialization.

■ 3. Amend § 801.2 by adding paragraph (g) to read as follows:

§ 801.2 Acquiring and acquired persons.

* * * * *

(g) Transfers of patent rights within NAICS Industry Group 3254.

(1) This paragraph applies only to patents covering products whose manufacture and sale would generate revenues in NAICS Industry Group 3254, including:

325411 Medical and Botanical Manufacturing
325412 Pharmaceutical Preparation Manufacturing
325413 In-Vitro Diagnostic Substance Manufacturing
325414 Biological Product (except Diagnostic) Manufacturing

(2) The transfer of patent rights covered by this paragraph constitutes an asset acquisition; and

(3) Patent rights are transferred if and only if all commercially significant rights to a patent, as defined in § 801.1(o), for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. All commercially significant rights are transferred even if the patent holder retains limited manufacturing rights, as defined in § 801.1(p), or co-rights, as defined in § 801.1(q).

Examples: Although these examples refer to licenses, which are typically used to effect the transfer of pharmaceutical patent rights to a recipient of those rights, other methods of transferring patent rights, by assignment or grant, among others, are similarly covered by these rules and examples.

1. B holds a patent relating to an active pharmaceutical ingredient for cardiovascular use. A will obtain a license from B that grants A the exclusive right to all of B's patent rights except that both A and B can manufacture the active pharmaceutical ingredient to be sold by A under the exclusive license agreement. B retains limited manufacturing rights as defined in § 801.1(p) because it retains the right to manufacture the product covered by the patent for cardiovascular use solely to provide the product to A. A is still receiving all commercially significant rights to the patent, and the transfer of these rights via the license constitutes an asset acquisition. Further, even if B retained all rights to manufacture (so that A could not manufacture), B would still retain limited manufacturing rights, and A would still receive all commercially significant rights to the patent. Thus, the transfer of these rights via the license would also constitute an asset acquisition.

2. B holds a patent for an in-vitro diagnostic substance relating to arthritis. B will grant A an exclusive license to all of B's patent rights for all veterinary indications. B retains all patent rights for all human indications. The exclusive license to all commercially significant rights for all veterinary indications is an asset acquisition because A is receiving all rights to the patent for a therapeutic area.

3. B holds a patent relating to a biological product. B will grant A an exclusive license to all of B's patent rights in all therapeutic areas. A and B are also entering into a co-development and co-commercialization agreement under which B will assist A in developing, marketing and promoting the product to physicians. B cannot separately use the patent in the same therapeutic area as A under the co-development and co-commercialization agreement. A will book all sales of the product and will pay B a portion of the profits resulting from those sales. Despite B's retention of these co-rights, A is still receiving all commercially significant rights. The licensing agreement is an asset acquisition. This would be an asset acquisition even if B also retained limited manufacturing rights.

4. B holds a patent relating to an active pharmaceutical ingredient and a bulk compound that contains that active pharmaceutical ingredient. B will grant A an exclusive license to use the bulk compound to manufacture and sell a finished product in the neurological therapeutic area. B cannot manufacture the active pharmaceutical ingredient or bulk compound for any other finished products in the neurological area, but it can manufacture either for use by another party in a different therapeutic area. Despite B's retention of manufacturing rights of the active pharmaceutical ingredient and bulk compound for therapeutic areas other than neurology, A is still receiving all commercially significant rights in a therapeutic area and the licensing agreement is the acquisition of an asset.

5. B holds a patent related to a pharmaceutical product that has been approved by the FDA. B will enter into an exclusive distribution agreement with A that will give A the right to distribute the product in the U.S. B will manufacture the product for A and will receive a portion of all revenues from the sale of the product. A receives no exclusive patent rights under the distribution agreement. A has not obtained all commercially significant rights to the patent because it is only handling the logistics of selling and distributing the product on B's behalf. Therefore, the exclusive distribution agreement is not an asset acquisition.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–27027 Filed 11–14–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2011–C–0878]

Listing of Color Additives Exempt From Certification; Spirulina Extract; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of September 13, 2013, for the final rule that appeared in the **Federal Register** of August 13, 2013. The final rule amended the color additive regulations to provide for the safe use of spirulina extract made from the dried biomass of the cyanobacteria *Arthrospira platensis* (*A. platensis*), as a color additive in candy and chewing gum.

DATES: The effective date for the final rule published August 13, 2013 (78 FR 49117), is confirmed as September 13, 2013.

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1264.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 13, 2013 (78 FR 49117), we amended the color additive regulations to add § 73.530 *Spirulina extract* (21 CFR 73.530) to provide for the safe use of spirulina extract made from the dried biomass of the cyanobacteria *A. platensis,* as a color additive in candy and chewing gum.

We gave interested persons until September 12, 2013, to file objections or

requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of August 13, 2013, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379 e) and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Office of Food Additive Safety, we are giving notice that no objections or requests for a hearing were filed in response to the August 13, 2013, final rule. Accordingly, the amendments issued thereby became effective September 13, 2013.

Dated: November 8, 2013.

Susan M. Bernard,

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

[FR Doc. 2013–27381 Filed 11–14–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA–2012–N–1238]

Medical Devices; Ophthalmic Devices; Classification of the Scleral Plug

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is classifying the scleral plug into class II (special controls), and exempting the scleral plugs composed of surgical grade stainless steel (with or without coating in gold, silver, or titanium) from premarket notification (510(k)) and continuing to require premarket notification (510(k)) for all other scleral plugs in order to provide a reasonable assurance of safety and effectiveness of the device. The scleral plug is a prescription device used to provide temporary closure of a scleral incision during an ophthalmic surgical procedure.

DATES: This final rule is effective on December 16, 2013.

FOR FURTHER INFORMATION CONTACT: Tina Kiang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2414, Silver Spring, MD 20993–0002, 301–796–6860, *Tina.Kiang@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), and Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the Agency takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.'' These devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of scleral plugs if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating.

II. Regulatory History of the Device

In the **Federal Register** of January 25, 2013 (78 FR 5327), FDA proposed to classify scleral plug devices used to provide temporary closure of a scleral incision during an ophthalmic surgical procedure into class II (special controls) and proposed special controls for these devices. FDA also proposed to exempt the devices from premarket notification requirements if the device is made from surgical grade stainless steel (with or without a gold, silver, or titanium coating). FDA invited interested persons to comment on the proposed regulation by April 25, 2013. FDA received no comments on the proposed rule.

III. Summary of Final Rule

In accordance with 21 CFR 860.84(g)(2), FDA is classifying scleral plugs into class II (special controls). FDA is codifying the classification of scleral plugs by adding § 886.4155. The Agency is also exempting these devices from premarket notification requirements when they are made from surgical grade stainless steel (with or without a gold, silver, or titanium coating). The Agency has also identified special controls for scleral plug devices. Following the effective date of this final classification rule, manufacturers will