Application No.	Drug	Applicant
NDA 18–354	ORTHO-NOVUM 10/11–21 and 10/11–28 (ethinyl estradiol; norethindrone) Tablets, 0.035 mg, 0.035 mg; 0.5 mg, 1 mg	Ortho McNeil Janssen Pharmaceuticals, Inc., 1125 Trenton Harbourton Rd., Titusville, NJ 08560
NDA 18–423	HIBICLENS (chlorhexidine gluconate) Topical Sponge, 4 %	Molnycke Health Care, 5550 Peachtree Parkway, Ste. 500, Norcross, GA 30092
NDA 19–436	PRIMACOR (milrinone lactate) Injection, Equivalent to (EQ) 1 mg base/milliliter	Sanofi Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19638 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–F–0320]

United States Pharmacopeial Convention; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the U.S. Pharmacopeial Convention has filed a petition proposing that the food additive regulations that incorporate by reference food-grade specifications from prior editions of the Food Chemicals Codex (FCC) be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1278.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4782) has been filed by U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852. The petition proposes that the food additive regulations in table 1 of this document, which incorporate by reference food-grade specifications from prior editions of the FCC, be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

TABLE 1.—LIST OF REGULATIONS

21 CFR Section	FCC Edition and/or Supplement Currently Referenced	Name of Additive	Current FCC Reference
172.167(b)	6th Ed.	Hydrogen peroxide	Meets FCC specifications.
172.320(b)(1)	3d Ed.	Amino acids	Meets FCC specifications.
172.345(b)	4th Ed.	Folic acid (folacin)	Meets FCC specifications.
172.379(b)	6th Ed.	Vitamin D_2	Meets FCC specifications.
172.380(b)	5th Ed.	Vitamin D_3	Meets FCC specifications.
172.665(d)(2)	4th Ed.	Gellan gum	Residual isopropyl alcohol limit not to exceed 0.075% by the procedure described in the Xanthan Gum monograph.
172.712(b)	4th Ed.	1,3-Butylene glycol	Conforms to FCC identity and specifications.
172.723(b)(3)	4th Ed.	Epoxidized soybean oil	Heavy metals (as lead) content cannot be more than 10 parts per million (ppm) as determined by the "Heavy Metals Test."
172.736(b)(2)	5th Ed.	Glycerides and polyglycides of hydrogenated vegetable oils	Acid value not greater than 2, and hydroxyl value, not greater than 56 as determined by "Acid Value" and "Hydroxyl Value" methods.

TABLE 1.—LIST OF REGULATIONS—Continued

21 CFR Section	FCC Edition and/or Supplement Currently Referenced	Name of Additive	Current FCC Reference
172.780(b)	5th Ed.	Acacia (gum arabic)	Meets FCC specifications.
172.800(b)(2)	3d Ed.	Acesulfame potassium	Fluoride content not more than 30 ppm as determined by Method III of the Fluoride Limit Test.
172.804(b)	3d Ed., 1st Supp.	Aspartame	Meets FCC specifications.
172.810	3d Ed.	Dioctyl sodium sulfosuccinate	Meets FCC specifications.
172.812(a)	3d Ed.	Glycine	Meets FCC specifications.
172.831(b)	4th Ed.	Sucralose	Meets FCC specifications.
172.833(b)(4)	4th Ed.	Sucrose acetate isobutyrate (SAIB)	Lead not to exceed 1.0 milligram/kilogram (mg/kg) determined by the "Atomic Absorption Spectrophotometric Graphite Furnace Method, Method I," with an attached modification to sample digestion section.
172.841(b)	5th Ed., 1st Supp.	Polydextrose	Meets FCC specifications.
172.846(b)	3d Ed.	Sodium stearoyl lactylate	Meets FCC specifications.
172.858(a)	3d Ed.	Propylene glycol alginate	Meets FCC specifications.
172.862(b)(1)	3d Ed.	Oleic acid derived from tall oil fatty acids	Meets FCC specifications except that titer (solidification point) shall not exceed 13.5 degrees Celsius and unsaponifiable matter shall not exceed 0.5%.
172.867(b)	4th Ed., 1st Supp.	Olestra	Meets FCC specifications.
172.869(b)(6)	4th Ed.	Sucrose oligoesters	Acid value not more than 4.0 as determined by the method "Acid Value," Appendix VII, Method I (Commercial Fatty Acids).
172.869(b)(7)	4th Ed.	Sucrose oligoesters	Residue on ignition not more than 0.7% as determined by "Residue on Ignition," Appendix IIC, Method I (using a 1 gram sample).
172.869(b)(8)	4th Ed., 1st Supp.	Sucrose oligoesters	Residual methanol not more than 10 mg/kg as determined by the method listed in the monograph for "Sucrose Fatty Acid Esters."
172.869(b)(9)	4th Ed., 1st Supp.	Sucrose oligoesters	Residual dimethyl sulfoxide not more than 2.0 mg/kg as determined by the method listed in the monograph "Sucrose Fatty Acid Esters."
172.869(b)(10)	4th Ed., 1st Supp.	Sucrose oligoesters	Residual isobutyl alcohol not more than 1.0 mg/kg as determined by the method listed in the monograph "Sucrose Fatty Acid Esters."
172.869(b)(11)	4th Ed.	Sucrose oligoesters	Lead not more than 1.0 mg/kg as determined by "Atomic Absorption Spectrophotometric Graphite Furnace Method," Method I.
173.115(b)(3)	4th Ed.	Alpha-acetolactate decarboxylase (*a*-ALDC) enzyme preparation derived from a recombinant Bacillus subtilis	Enzyme preparation must meet general and additional requirements for enzyme preparations in FCC.
173.160(d)	3d Ed.	*Candida guilliermondii*	Citric acid produced must conform to FCC specifications (under "Citric acid").

TABLE 1.—LIST OF REGULATIONS—Continued

21 CFR Section	FCC Edition and/or Supplement Currently Referenced	Name of Additive	Current FCC Reference
173.165(d)	3d Ed.	*Candida lipolytica*	Citric acid produced must conform to FCC specifications (under "Citric acid").
173.228(a)	4th Ed.	Ethyl acetate	Meets FCC specifications.
173.280(c)	3d Ed.	Solvent extraction process for citric acid	Meets FCC specifications.
173.310(c)	4th Ed.	Boiler water additives; Sodium carboxymethylcellulose	Contains not less than 95% sodium carboxymethylcellulose on a dry-weight basis, with maximum substitution of 0.9 carboxymethylcellulose groups per anhydroglucose unit, and with a minimum viscosity of 15 centipoises for 2% by weight aqueous determined by the method cited in FCC.
173.310(c)	4th Ed.	Boiler water additives; Sorbitol anhydride esters	Meets FCC specifications.
173.368(c)	4th Ed.	Ozone	Meets FCC specifications.
178.1005(c)	3d Ed.	Hydrogen peroxide solution	Meets FCC specifications.
180.25(b)	3d Ed.	Mannitol	Meets FCC specifications.
180.30(a)	3d Ed.	Brominated vegetable oil	Meets FCC specifications.
180.37(b)	3d Ed.	Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin	Meets FCC specifications.

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 4, 2010.

Catherine L. Copp,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2010–19722 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 7, 2010, 8:30 a.m. to September 8, 2010, 12 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on July 22, 2010, 75 FR42758.

This amendment has been processed to change the start and end times of the NCAB meeting. The meeting will now start at 4 p.m. and end at 5:45 p.m. on September 7, 2010. On September 8, 2010, the closed session will be held from 8:30 a.m. to 10 a.m. The open session will start at 10:15 a.m. and end at 5 p.m.

Dated: August 4, 2010.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–19681 Filed 8–9–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Griffithsin, Glycosylation-Resistant Griffithsin, and Related Conjugates as Biotherapeutics for the Treatment of HIV and HCV Infections

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the inventions embodied in:

1. U.S. Provisional Patent Application Serial No. 60/576,056, filed on June 1, 2004, entitled "Griffithsin, Glycosylation-Resistant Griffithsin, and Related Conjugates, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production And Methods of Use", converted to PCT/US2005/18778, filed May 27, 2005, and entered national stage in U.S. (patent application serial number 11/569,813), Canada (patent application serial number 2,567,728), Australia (patent application serial number 2005250429), Europe (patent application serial number 05804849.7), Japan (patent application serial number 2007–515398), Israel (patent application serial number 179236), New Zealand (patent number 2006/09573), and South Africa (patent application serial number 2006/09573) (HHS reference E–106–2003/0) from Dr. Barry O'Keefe *et al.* (NCI).

2. U.S. Provisional Patent Application Serial No. 60/741.403, filed on