PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I—[Amended]

■ 1. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 221(m), 702(a) (5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 2. Amend § 416.924 by revising paragraph (g) to read as follows:

§ 416.924 How we determine disability for children.

* * * * *

(g) *How we will explain our findings.* When we make a determination or decision whether you are disabled under this section or whether your disability continues under § 416.994a, we will indicate our findings at each step of the sequential evaluation process as we explain in this paragraph. At the initial and reconsideration levels of the administrative review process, State agency medical and psychological consultants will indicate their findings in writing in a manner that we prescribe. The State agency medical or psychological consultant (see § 416.1016) or other designee of the Commissioner has overall responsibility for completing the prescribed writing and must sign the prescribed writing to attest that it is complete, including the findings of fact and any discussion of supporting evidence. Disability hearing officers, administrative law judges and the administrative appeals judges on the Appeals Council (when the Appeals Council makes a decision) will indicate their findings at each step of the sequential evaluation process in their determinations or decisions. In claims adjudicated under the procedures in part 405 of this chapter, administrative law judges will also indicate their findings at each step of the sequential evaluation process in their decisions.

[FR Doc. 2011–17859 Filed 7–14–11; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2010–F–0103]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Hydroxypropyl Cellulose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for hydroxypropyl cellulose by lowering the minimum permitted viscosity from 145 centipoises (cPs) to 10 cPs and to permit its use as a binder in dietary supplements. This action is in response to a petition filed by Nisso America, Inc.

DATES: This rule is effective July 15, 2011. Submit either electronic or written objections and requests for a hearing by August 15, 2011. See section VII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2010–F–0103, 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:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM 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 Agency name and Docket No. FDA–2010–F–0103 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 of this document.

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 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. Background

In a notice published in the **Federal Register** of April 8, 2010 (75 FR 17928), FDA announced that Nisso America Inc., 45 Broadway, Suite 2120, New York, NY 10006, filed a food additive petition (FAP 0A4780). The petition proposed to amend the food additive regulations in § 172.870 (21 CFR 172.870), by lowering the minimum permitted viscosity of hydroxypropyl cellulose (HPC) identified in § 172.870(a)(1) from 145 cPs to 10 cPs and to permit its use as a binder in dietary supplements.

Section 172.870 includes both high-substituted HPC, which contains not more than 4.6 hydroxypropyl groups per anhydroglucose unit (§ 172.870(a)(1)), and low-substituted HPC, which contains on average 0.1 to 0.4 hydroxypropyl groups per anhydroglucose unit (§ 172.870(a)(2)). High-substituted HPC can be used, in accordance with good manufacturing practice, as an emulsifier, film former, protective colloid, stabilizer, suspending agent and thickener (§ 172.870(b)(1)). Low-substituted HPC can be used, in accordance with good manufacturing practice, as a binder and disintegrator in tablets or wafers containing dietary supplements (§ 172.870(b)(2)). It is the high-substituted HPC regulated under § 172.870(a)(1) and (b)(1) that is the subject of this petition.

II. Evaluation of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.'' To establish with reasonable certainty that

a food additive is not harmful under its intended conditions of use, FDA considers the estimated human dietary intake of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to the Agency.

Both high-substituted HPC (the subject of this petition) and low-substituted HPC are forms of cellulose and cellulose derivatives. The safety of cellulose and cellulose derivatives has been studied extensively in animals and humans. These studies show that cellulose and cellulose derivatives pass unchanged through the gastrointestinal tract and can be quickly detected in the feces of test animals and humans when consumed, confirming that the consumption of cellulose and cellulose derivatives at the proposed viscosity and use level will not result in toxicity. The Joint Food and Agriculture Organization and the World Health Organization (FAO/WHO) Expert Committee for Food Additives (JECFA) has evaluated the food uses of modified celluloses, including HPC, and has concluded that, as a group, modified celluloses are of very low toxicity at the levels of intake necessary to achieve the desired effect and do not pose a hazard to health (Ref. 1). Viscosity is not specified by the JECFA as a factor related to the safety of these additives.

Although there is no available safety testing directly on HPC with a viscosity of < 145 cPs, there have been numerous studies on the viscosity related safety effect for other modified celluloses. Most of the safety studies we reviewed analyzed the use of cellulose and cellulose derivatives. All of these studies support the assertion that there is no safety effect arising from a change in viscosity. Because high-substituted HPC with a minimum viscosity of 10 cPs is not expected to have significantly different biological properties than those cellulose and cellulose derivatives which have been studied, or the high and low-substituted HPC currently permitted under § 172.870, FDA concludes that the proposed use of high-substituted HPC with a minimum viscosity of 10 cPs is safe.

Lastly, because high-substituted HPC with a minimum viscosity of 10 cPs is intended to be used for the same purposes as are currently permitted for either high and low-substituted HPC, including as a binder in dietary supplements, FDA concludes that the proposed changes to § 172.870 will not result in an increase in the combined overall daily intake of high-substituted and low-substituted HPC. Thus, permitting the use of high-substituted HPC with a minimum viscosity of 10 cPs for use as a binder in dietary supplements will not result in an increased intake or harm to human health under the established conditions of use.

III. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the petitioned use of high-substituted HPC with a minimum viscosity of 10 cPs as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener in food, and as a binder in dietary supplements. Based on this information, FDA concludes that the proposed use of the additive is safe and will achieve its intended technical effect under the proposed conditions of use. Therefore, the regulations in 21 CFR part 172 should be amended as set forth in this document.

IV. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Environmental Impact

The Agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 0A4780 (75 FR 17928). No new information or comments have been received that would affect the Agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. 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.

VII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. 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. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all 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.

VIII. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

FDA's review of this petition was limited to section 409 of 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) (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 exceptions in section 301(ll)(1) to (ll)(4) applies. In our review of this petition, FDA did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this 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 food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

IX. References

The following reference has 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. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

1. Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), Hydroxypropyl Cellulose Toxicology Monograph 687, FAS 26–JECFA 35/85, 1989; *http://apps.who.int/ipsc/database/evaluations/search.aspx.*

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

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 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Section 172.870 is amended by revising paragraphs (a)(1) and (b)(1) to read as follows:

§ 172.870 Hydroxypropyl cellulose.

* * * * *

(a) * * *

(1) A cellulose ether containing propylene glycol groups attached by an ether linkage that contains, on an anhydrous basis, not more than 4.6 hydroxypropyl groups per anhydroglucose unit. The additive has a minimum viscosity of 10 centipoises for a 10 percent by weight aqueous solution at 25 degrees C.

* * * * *

(b) * * *

(1) The additive identified in paragraph (a)(1) of this section is used or intended for use as an emulsifier, film former, protective colloid, stabilizer, suspending agent, or thickener in food, in accordance with good manufacturing practice. The additive also may be used as a binder in dietary supplements, in accordance with good manufacturing practice.

* * * * *

Dated: July 6, 2011.

Susan M. Bernard,

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

[FR Doc. 2011–17928 Filed 7–14–11; 8:45 am]

BILLING CODE 4160–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in August 2011. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective August 1, 2011.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Manager, Regulatory and Policy Division, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for August 2011.[1]

The August 2011 interest assumptions under the benefit payments regulation will be 2.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for July 2011, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during August 2011, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE–EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.