

interest is preserved in properties acquired with public funds. The rule further ensures compliance with all

other Federal statutes applicable to the expenditure of Federal funds when acquiring real property.

*Respondents:* Head Start and Early Head Start grantees and delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Regulation .....	200	1	41	8,200.

*Estimated Total Annual Burden Hours:* 8,200

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: [Katherine\\_T.\\_Astrich@omb.eop.gov](mailto:Katherine_T._Astrich@omb.eop.gov).

Dated: June 8, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 06-5437 Filed 6-14-06; 8:45 am]

**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2006F-0225]

**Georgia-Pacific Resins, Inc.; Filing of Food Additive Petition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Georgia-Pacific Resins, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glycerol ester of tall oil rosin to adjust the density of

citrus oils used in the preparation of beverages and to provide for the use of steam stripping as a purification method for producing glycerol ester of wood rosin, gum rosin, or tall oil rosin.

**FOR FURTHER INFORMATION CONTACT:**

Clarence W. Murray III, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1311.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 6A4765) has been filed by Georgia-Pacific Resins, Inc., P.O. Box 105734, Atlanta, GA 30348. The petition proposes to amend the food additive regulations in § 172.735 *Glycerol ester of wood or gum rosin* (21 CFR 172.735) to provide for the following: (1) The safe use of glycerol ester of tall oil rosin to adjust the density of citrus oils used in the preparation of beverages; and (2) the use of steam stripping as a purification method for producing glycerol ester of wood rosin, gum rosin, or tall oil rosin.

The agency has 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. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 24, 2006.

**Laura M. Tarantino,**

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

[FR Doc. E6-9319 Filed 6-14-06; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005D-0200]

**International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Final Guidance for Industry on "Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products;" Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#177) entitled "Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products" (VICH GL40). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides general principles through recommendations on the setting and justification, to the extent possible, of a uniform set of international specifications for biotechnological and biological products to support new marketing applications.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: [dennis.bensley@fda.hhs.gov](mailto:dennis.bensley@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

**II. Guidance on Biotechnological/Biological Veterinary Medicinal Products**

In the **Federal Register** of May 27, 2005 (70 FR 30763), FDA published the notice of availability of the VICH draft guidance, giving interested persons until June 27, 2005, to submit comments. No comments were received. At a meeting held on November 2005, the VICH Steering Committee endorsed the final guidance for industry, (VICH GL-40).

This VICH guidance document provides general principles through recommendations on the setting and justification, to the extent possible, of a uniform set of international specifications for biotechnological and biological products to support new marketing applications. The recommendations in this document apply to products composed of well-characterized proteins and polypeptides, and their derivatives which are isolated from tissues, body fluids, cell cultures, or produced using recombinant deoxyribonucleic acid (r-DNA) technology. Thus, the document covers the generation and submission of specifications for products such as cytokines, growth hormones and growth factors, insulins, and monoclonal antibodies. This document does not cover antibiotics, heparins, vitamins, cell metabolites, DNA products, allergenic extracts, vaccines, cells, whole blood, and cellular blood components.

**III. Paperwork Reduction Act of 1995**

This guidance document refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 514.1 have been approved under OMB Control No. 0910-0032 (expiration date 12/31/2007).

**IV. Significance of Guidance**

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "require," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

The VICH guidance (#177) is consistent with the agency's current thinking on the Biotechnological/Biological Veterinary Medicinal Products. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

**V. Comments**

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**VI. Electronic Access**

Copies of the guidance document entitled "Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products" (VICH GL40) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: June 6, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-9324 Filed 6-14-06; 8:45 am]

**BILLING CODE 4160-01-S**