TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours Per Recordkeeper	Total Hours
807.31	16,200	4	64,800	.50	32,400
Total Burden Hours					32,400

The burdens are explained as follows:

The annual reporting burden hours to respondents for registering establishments and listing devices is estimated to be 9,450 hours, and recordkeeping burden hours for respondents is estimated to be 32,400 hours. The estimates cited in tables 1A, 1B, and 2 of this document are based primarily upon the annual FDA accomplishment report, which includes actual FDA registration and listing figures from fiscal year (FY) 2003. These estimates are also based on FDA estimates of FY 2003 data from current systems, conversations with industry and trade association representatives, and from internal review of the documents referred to in tables 1A, 1B, and 2 of this document.

According to 21 CFR part 807, all owners/operators are required to list, and establishments and U.S. agents are required to register. Each owner/operator has an average of two establishments, according to statistics gathered from FDA's registration and listing database. The database has 25,100 active establishments listed in it. Based on past experience, the agency anticipated that approximately 7,300 registrations will be processed during the first year, and 3,100 thereafter. FDA anticipates reviewing 200 historical files annually.

Dated: January 7, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–676 Filed 1–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004F–0546]

Alltech, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Alltech, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyurethane polymer coating in ruminant feed.

DATES: Submit written or electronic comments by March 29, 2005.

ADDRESSES: Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Isabel Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, email: *ipocurull@cvm.fda.gov*.

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 2253) has been filed by Alltech, Inc., 3031 Catnip Hill Pike, Nicholasville, KY 40356. The petition proposes to amend the food additive regulations in part 573 *Food Additives permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of polyurethane polymer coating in ruminant feed.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see **ADDRESSES**) for public review and comment.

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.

FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: January 3, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–673 Filed 1–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0549]

Draft Guidance for Industry on Labeling Over-the-Counter Human Drug Products; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This guidance is intended to assist manufacturers, packers, and distributors of over-the-counter (OTC) drug products to implement the agency's regulation on standardized content and format requirements for the labeling of OTC drug products. This draft guidance discusses labeling questions that have been frequently asked by manufacturers, packers, and distributors in implementing the new requirements. The labeling examples in this draft guidance show various format and content features and suggest how OTC drug monograph labeling information finalized before the new

requirements can be converted to the new format.

DATES: Submit written or electronic comments on the draft guidance for industry by March 14, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cazemiro R. Martin or Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Questions and Answers.'' This is one of several draft guidances the agency is developing to help manufacturers, packers, and distributors implement the regulation establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these draft guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (21 CFR 201.66). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively.

The regulation for this standardized labeling requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format will require revision of all labeling in use before the compliance date of the final rule. The final rule covers all OTC drug and drug-cosmetic products, whether marketed under a new drug marketing application, abbreviated new drug application, or OTC drug monograph (or product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquires from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. This draft guidance discusses those inquiries and provides labeling examples to show various format and content features of the labeling requirements and suggest how OTC drug monograph labeling finalized before the new regulation was issued can be converted to the new format. This draft guidance also discusses how to list inactive ingredients that may or may not be contained in the OTC drug product.

This level I draft guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The draft guidance includes labeling examples that are consistent with the new OTC drug products standardized labeling content and format. The draft guidance represents the agency's current thinking on how OTC drug monograph labeling can be converted to the new OTC ''Drug Facts'' format labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 28, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–696 Filed 1–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Surveys of Safety Net Providers for the Healthy Communities Access Program National Evaluation—New

The Bureau of Primary Health Care, Health Resources and Services Administration, is conducting a national evaluation of the Healthy Communities Access Program (HCAP) as required by section 340(i) of the Public Health Service Act (42 U.S.C. 256) Public Law 107–251, Oct. 26, 2002.

Surveys of Safety Net Providers and Consortium Leaders will be performed to provide essential information not otherwise available for the national evaluation. Based on consortia response rates of 70% for the provider survey and 75% for the consortia leader survey, it is estimated that 405 Safety Net Providers and 145 Consortia Leaders will complete the surveys.

A preliminary review of the sampling frame for safety net providers indicates that the allocated sample provides adequate representation of all provider types of interest. Legislatively required provider members of HCAP consortia are included in the sample, *i.e.*, hospitals, federally qualified health centers, public health departments, and public/private providers that serve the medically underinsured and underserved. The survey results will be considered along with information from other quantitative and qualitative data