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