including occupational history and smoking history. The data collected are used by scientists for research purposes in defining the diagnostic criteria for pneumoconiosis and in correlating pathologic changes with exposures and x-ray findings.

There are no costs of the NCWAS to respondents other than their time. The total estimated burden hours are 4,470.

Type of respondent	Form name	Number of respondents	Responses per respondent	Average burden per response (in hours)
Physicians B Readers	Roentgenographic Interpretation Form—CDC/NIOSH (M) 2.8.	10,000	1	3/60
	Interpreting Physician Certification Document—CDC/NIOSH (M) 2.12.	300	1	10/60
Miners	Miner Identification Document—CDC/NIOSH (M) 2.9	5,000	1	20/60
	No form—X-ray	5,000	1	15/60
	No form—Spirometry	2,500	1	20/60
Coal Mine Operators	Coal Mine Operator's Plan—CDC/NIOSH (M) 2.10	200	1	30/60
Supervisor at X-ray Facilities	Facility Certification Document—CDC/NIOSH (M) 2.11	100	1	30/60
Pathologist	No form—Invoice	50	1	5/60
	No form—Final Diagnosis Report	50	1	5/60
Next-of-Kin	Consent, Release, and History Form—CDC/NIOSH (M) 2.6	50	1	15/60

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–9922 Filed 4–22–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0125]

Draft Guidance for Industry and Food and Drug Administration Staff; Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007." This draft guidance provides information on how a manufacturer may demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. In this draft guidance, FDA provides recommendations on the evidence that a manufacturer may use to demonstrate that a tobacco product was commercially marketed in the United States as of February 15, 2007. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 24, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: With regard to the draft guidance: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, e-mail: *annette.marthaler@fda.hhs.gov.*

With regard to the proposed collection of information: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. In this draft guidance, FDA provides recommendations on the information that a manufacturer may use to establish that a tobacco product was commercially marketed in the United States on February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review requirements. In the draft guidance document, FDA recommends that this information may include, among other things, dated copies of advertisements, dated catalog pages, and dated promotional material.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on "Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007." 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 approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

An electronic version of the draft guidance document is available on the Internet at *http://www.regulations.gov*

and *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007—(OMB Control Number 0910–NEW)

This draft guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007, and is, therefore, a grandfathered product not subject to premarket review. The draft guidance recommends that the manufacturer provide evidence that may include, among other things, dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading. FDA recommends that the manufacturer submit as much information as possible to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. FDA's estimate of the number of respondents is based on the fact that requesting an agency determination of the grandfathered status of a tobacco product under the draft guidance is not required and also on indications of interest in making such request. The number of hours is FDA's estimate of how long it might take one to review, gather, and submit dated information if making a request for an agency determination.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ONE TIME REPORTING BURDEN [1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	150	1	150	10	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: April 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–9939 Filed 4–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–F–0225]

Ferm Solutions, Inc.; Filing of Food Additive Petition (Animal Use); Erythromycin Thiocyanate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ferm Solutions, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in byproduct distiller grains used as an animal feed or feed ingredient.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by May 25, 2011.

ADDRESSES: Submit electronic comments to: *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, e-mail: *isabel.pocurull@fda.hhs.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 2271) has been filed by Ferm Solutions, Inc., P.O. Box 203, 445 Roy Arnold Ave., Danville, KY 40423. 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 erythromycin thiocyanate as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its