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Draft Guidance on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007—(OMB Control Number 0910–NEW)

This draft guidance provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007, and is,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 The draft guidance recommends that the manufacturer provide evidence that may include, among other things, dated copies of advertisements, dated catalog pages, dated promotional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

consequent presence in byproduct distiller grains used as an animal feed or feed ingredient.

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 **DATES** and **ADDRESSES**) for public review and comment.

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. 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: April 15, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–9913 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–2010–D–0431]

Guidance for Food and Drug Administration Staff and Tobacco Retailers on Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." This guidance document describes FDA's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) relating to tobacco products, including the FD&C Act requirement that tobacco products may not be sold or distributed in violation of FDA's "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents." With the release of this final guidance document, several provisions in the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) that relate to civil money penalties and no-tobacco-sale orders become effective.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers" 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 electronic access to the guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–287–1373, *gerie.voss@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for FDA staff and tobacco retailers entitled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." On June 22, 2009, President Obama signed the Tobacco Control Act (Pub. L. 111–31) into law. The Tobacco Control Act grants FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Among its many provisions, the Tobacco Control Act authorizes FDA to impose civil money penalties for violations of the FD&C Act requirements that relate to tobacco products (section 303(f)(9) of the FD&C Act (21 U.S.C. 333(f)(9)). Of special interest to retailers, one of the FD&C Act's requirements is that tobacco products may not be sold or distributed in a manner that violates regulations issued under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)), such as the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" that were published by FDA on March 19, 2010 (75 FR 13225) (21 CFR part 1140). The Tobacco Control Act also authorizes FDA to impose a no-tobacco-sale order on a retail outlet for repeated violations of regulations issued under section 906(d) of the FD&C Act, and discusses a number of technical and procedural issues relating to civil money penalties and no-tobacco-sale orders.

This guidance document describes the penalty structure and FDA policies with respect to civil money policies and no-tobacco-sale orders. With the release of this final guidance document, several Tobacco Control Act provisions that relate to civil money penalties and no-tobacco-sale orders become effective (section 103(q)(3) of the Tobacco Control Act).

In the **Federal Register** of August 31, 2010 (75 FR 53316), FDA announced the availability of the draft guidance of the same title dated August 2010. FDA received a few comments on the draft guidance, and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers." 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. 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.