

Translational Science Awards (CTSA) Initiative. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The CTSA Initiative is directed at transforming the way biomedical research is conducted nationwide by reducing the time it takes for basic science or laboratory discoveries to become treatments for patients, and for those treatments in turn to be incorporated and disseminated throughout community practice. The primary purpose of this data collection is to provide information about the process and early outcomes associated with 46 awardees participating in the first four cohorts of CTSA awards, in order to fulfill the

congressional expectations for external program evaluation. NIH will use the results to understand the extent to which the CTSA Initiative is bringing about transformational changes in clinical and translational science among academic medical centers and their research partners, increasing the efficiency of the research process, and enhancing the capacity of the field to conduct clinical and translational research. All information collected will be used to provide analytical and policy support to NCRR, assisting NIH in making decisions about current CTSA programming, future funding, and other initiatives to improve clinical and translational science. It may also

provide information for NIH's Government Performance and Results Act (GPRA) report. *Frequency of Response:* Biennial. *Affected Public:* Individuals. *Type of Respondents:* Scientific researchers. The annual reporting burden is as follows: *Estimated Number of Respondents:* 3,563; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.13; *Estimated Total Annual Burden Hours Requested:* 451.5. The annualized cost to respondents is estimated at \$14,056. There are no capital or start-up costs, and no maintenance or service cost components to report.

Respondent type	Estimated number of respondents	Estimated number of hours per respondent type	Frequency of response	Estimated total annual burden hours requested
Users survey	500	.25	.5	62.5
Nonusers survey	500	.08	.5	20
Trainees/scholars survey	1,213	.33	.5	200
Mentors survey	1,350	.25	.5	169
Total				451.5

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Patricia Newman, Program Analyst, Office of Science Policy, National Center for Research Resources, 6701 Democracy Boulevard, MSC 4874, Bethesda, Maryland 20892-4874, or e-mail your request, including your address to pnewman@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if

received within 60 days of the date of this publication.

Dated: October 4, 2010.

Patricia Newman,

Program Analyst, Office of Science Policy, NCRR, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; the Atherosclerosis Risk in Communities Study (ARIC)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: The Atherosclerosis Risk in Communities Study (ARIC). *Type of Information Collection Request:* Revision of a currently approved collection (OMB NO. 0925-0281). *Need and Use of*

Information Collection: ARIC will conduct a clinical examination of the cohort over a 24-month period (May 2011 to April 2013). In addition, this project involves biennial follow-up by telephone of participants in the ARIC study, review of their medical records, and interviews with doctors and family to identify disease occurrence.

Interviewers will contact doctors and hospitals to ascertain participants' cardiovascular events. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. *Frequency of Response:* The participants will be contacted bi-annually for follow-up. A subset of the cohort may choose to volunteer for the clinical examination; these individually will be contacted once in a 3 year period. *Affected Public:* Individuals or households; Businesses or other for profit; Small businesses or organizations. *Type of Respondents:* Individuals or households; doctors and staff of hospitals and nursing homes. The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,673; *Estimated Number of Responses per Respondent:* 2.7; *Average Burden Hours Per Response:* 0.5916; and *Estimated Total Annual Burden Hours Requested:* 20,434. The annualized cost to respondents is estimated at \$355,882, assuming

respondents time at the rate of \$17.00 per hour and physician time at the rate of \$75.00 per hour. There are no Capital

Costs to report. There are no Operating or Maintenance Costs to report.

TABLE A.12.1 ESTIMATES OF HOUR BURDEN

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Participants	10,933	3	0.6165	20220.6.
Physician (or coroner) (for CHD)	420	1	0.1667	70.
Physician (for heart failure)	920	1	0.0833	76.6.
Participants' next of kin	400	1	0.1667	66.7.
Totals	12,673	20433.9 or 20434.

Note: Reported and calculated numbers differ slightly due to rounding.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

For Further Information: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Hanyu Ni, Project Officer, NIH, NHLBI, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0448 or E-mail your request, including your address to: NiHanyu@nhlbi.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: October 6, 2010.

Suzanne Freeman,

NHLBI Project Clearance Liaison, National Institutes of Health.

Michael Lauer,

Director, DCVS, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-F-0510]

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

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 virginiamycin as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product distiller grains used as an animal feed or feed ingredient.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by November 12, 2010.

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 2264) has been filed by Ferm Solutions, Inc., PO Box 203, Danville, KY 40422. 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 virginiamycin as an antimicrobial processing aid in fuel-ethanol fermentations with respect to its consequent presence in by-product 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).