

Information Collection: Collection Requirements for Compendia for Determination of Medically-accepted Indications for Off-label Uses of Drugs and Biologicals in an Anti-cancer Chemotherapeutic Regimen *Use:* Congress enacted the Medicare Improvement of Patients and Providers Act (MIPPA). Section 182(b) of MIPPA amended Section 1861(t)(2)(B) of the Social Security Act (42 U.S.C. 1395x(t)(2)(B)) by adding at the end the following new sentence: 'On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interest.' We believe that the implementation of this statutory provision that compendia have a "publicly transparent process for evaluating therapies and for identifying potential conflicts of interests" is best accomplished by amending 42 CFR 414.930 to include the MIPPA requirements and by defining the key components of publicly transparent processes for evaluating therapies and for identifying potential conflicts of interests.

All currently listed compendia will be required to comply with these provisions, as of January 1, 2010, to remain on the list of recognized compendia. In addition, any compendium that is the subject of a future request for inclusion on the list of recognized compendia will be required to comply with these provisions. No compendium can be on the list if it does not fully meet the standard described in section 1861(t)(2)(B) of the Act, as revised by section 182(b) of the MIPPA. *Form Number:* CMS-10302 (OMB#: 0938-1078); *Frequency:* Reporting, Recordkeeping and Third-party disclosure; *Affected Public:* Business and other for-profit and Not-for-profit institutions; *Number of Respondents:* 845; *Total Annual Responses:* 900; *Total Annual Hours:* 5,135. (For policy questions regarding this collection contact Brijet Burton at 410-786-7364. For all other issues call 410-786-1326.)

7. Type of Information Collection
Request: Reinstatement without change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease (ESRD) Medical Information Facility Survey; *Form Number:* CMS-2744 (OMB#: 0938-0447); *Use:* The End Stage Renal Disease (ESRD) Medical Information Facility Survey form (CMS-2744) is completed annually by Medicare-approved providers of dialysis and transplant services. The CMS-2744 is designed to

collect information concerning treatment trends, utilization of services and patterns of practice in treating ESRD patients. The information is used to assess and evaluate the local, regional and national levels of medical and social impact of ESRD care and is used extensively by researchers and suppliers of services for trend analysis. The information is available on the CMS Dialysis Facility Compare website and will enable patients to make informed decisions about their care by comparing dialysis facilities in their area. *Frequency:* Yearly; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 5,465; *Total Annual Responses:* 5,465; *Total Annual Hours:* 43,720. (For policy questions regarding this collection contact Connie Cole at 410-786-0257. For all other issues call 410-786-1326.)

8. Type of Information Collection
Request: Reinstatement without change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Death Notification P.L. 95-292; 42 CFR 405.2133, 45 CFR 5-5b; 20 CFR Parts 401 and 422E *Use:* The ESRD Death Notification (CMS-2746) is completed by all Medicare-approved ESRD facilities upon the death of an ESRD patient. Its primary purpose is to collect fact of death and cause of death of ESRD patients. Certain other identifying information (e.g., name, Medicare claim number, and date of birth) is required for matching purposes. Federal regulations require that the ESRD Networks examine the mortality rates of every Medicare-approved facility within its area of responsibility. The Death Form provides the necessary data to assist the ESRD Networks in making decisions that result in improved patient care and in cost-effective distribution of ESRD resources. The data is used by the ESRD Networks to verify facility deaths and to monitor facility performance. *Form Number:* CMS-2746 (OMB#: 0938-0448); *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 5,173; *Total Annual Responses:* 82,768; *Total Annual Hours:* 41,384. (For policy questions regarding this collection contact Connie Cole at 410-786-0257. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number,

and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 19, 2010. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-6974, E-mail: OIRA_submission@omb.eop.gov.

Dated: June 15, 2010.

Michelle Shortt,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0083]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 19, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0339. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr.,

P150—400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—(OMB Control Number 0910–0339)—Extension

This information collection was established because epidemiological

evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain or may contain protein derived from

mammalian tissue, and feeds made from such products.

In the **Federal Register** of February 26, 2010 (75 FR 8959), FDA published a 60-day notice requesting public comment on the proposed collection of information. In response, FDA received one comment. This comment was outside the scope of the four topics discussed in the 60-day notice.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
589.2000(e)(1)(iv)	400	1	400	14	5,600

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

Dated: June 14, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0267]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on Consumers' Emotional and Cognitive Reactions to Food Recalls

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey on Consumers' Emotional and Cognitive Reactions to Food Recalls.

DATES: Submit either electronic or written comments on the collection of information by August 17, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://>

www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the 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.

Survey on Consumers' Emotional and Cognitive Reactions to Food Recalls—21 U.S.C. 393(d)(2)(C) (OMB Control Number 0910–NEW)

I. Background

The proposed “Survey on Consumers' Emotional and Cognitive Reactions to Food Recalls” will be conducted under a cooperative agreement between the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and the Center for Risk Communication Research at the University of Maryland. JIFSAN was established in 1996 and is a public and private partnership between FDA and the University of Maryland. The Center for Risk Communication Research will design and administer the study.

The proposed study will assess consumers' emotional and cognitive recollection of certain food recalls and gauge how these recollections affect their current perceptions about food recalls and their inclination to adhere to future recommended food recall behaviors. Existing data show that many consumers do not take appropriate protective actions during a foodborne illness outbreak or food recall (Refs. 1