

<http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?page=action=displayproduct&productID=1620>.

This notice is to notify the public that the EHC program would find the following information on *imaging tests for the diagnosis and staging of pancreatic adenocarcinoma* helpful:

- A list of completed studies your company has sponsored for this indication. In the list, *indicate whether results are available on*

ClinicalTrials.gov along with the *ClinicalTrials.gov* trial number.

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies your company has sponsored for this indication*. In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the Effective Health Care Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EHC program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is also available online at: <http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?page=action=displayproduct&productID=1620>.

The Key Questions

Question 1

What is the comparative effectiveness of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) for diagnosis of pancreatic adenocarcinoma in adults with suspicious symptoms?

a. What is the accuracy of each imaging technique for diagnosis and assessment of resectability?

b. What is the comparative accuracy of the different imaging techniques for diagnosis and assessment of resectability?

c. What is the comparative diagnostic accuracy of using a single imaging technique versus using multiple imaging techniques?

d. How is test experience (e.g., operative experience, assessor experience, center's annual volume) related to comparative diagnostic accuracy of the different imaging strategies?

e. How are patient factors and tumor characteristics related to the comparative diagnostic accuracy of the different imaging strategies?

f. What is the comparative clinical management after the different imaging strategies when used for diagnosis?

What is the comparative impact of the different imaging strategies on long-term survival and quality of life when used for diagnosis?

Question 2

What is the comparative effectiveness of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) for *staging* of pancreatic adenocarcinoma among adults with a diagnosis of pancreatic adenocarcinoma?

a. What is the staging accuracy of each imaging technique (for tumor size, lymph node status, vessel involvement, metastases, stage [I–IV], and resectability)?

b. What is the comparative staging accuracy among the different imaging techniques?

c. What is the comparative staging accuracy of using a single imaging technique versus using multiple imaging techniques?

d. How is test experience (e.g., operative experience, assessor experience, center's annual volume) related to comparative staging accuracy of the different imaging strategies?

e. How are patient factors and tumor characteristics related to the comparative staging accuracy of the different imaging strategies?

f. What is the comparative clinical management of the different imaging strategies when used for staging?

What is the comparative impact of the different imaging strategies on long-term survival and quality of life when used for staging?

Question 3

What are the rates of harms of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) when used to diagnose and/or stage pancreatic adenocarcinoma?

a. How are patient factors related to the harms of different imaging techniques?

What are patient perspectives on the tolerance of different imaging techniques and the balance of benefits and harms of different imaging techniques?

Question 4

What is the comparative screening accuracy of imaging techniques (e.g., MDCT angiography ± 3D reconstruction, other MDCT, EUS–FNA, PET–CT, MRI) in high-risk asymptomatic adults (i.e., those at genetic or familial risk of pancreatic adenocarcinoma)?

Dated: August 19, 2013.

Carolyn M. Clancy,
AHRQ, Director.

[FR Doc. 2013–20849 Filed 8–26–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0520]

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; Extension

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 September 26, 2013.

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 emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0339 and title "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRStaff@fda.hhs.gov.

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—21 CFR 589.2000(e)(1)(iv)—(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.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means, and

specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

In the **Federal Register** of May 16, 2013 (78 FR 28852), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintaining written procedures (§ 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: August 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-20821 Filed 8-26-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0938]

Draft Guidance for Industry on Abbreviated New Drug Applications: Stability Testing of Drug Substances and 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 "ANDAs: Stability

Testing of Drug Substances and Products, Questions and Answers." This draft guidance clarifies stability testing recommendations for abbreviated new drug applications (ANDAs) by providing responses to public comments in a questions-and-answers format. This draft guidance addresses public comments regarding FDA's recommendation to generic drug manufacturers to follow International Conference on Harmonisation (ICH) stability guidances Q1A (R2) through Q1E.

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 on 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 October 28, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for

Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD-640), Food and Drug Administration, 7500 Standish Pl., MPN2, Rm. 243, Rockville, MD 20855, 240-276-8546.

SUPPLEMENTARY INFORMATION: