identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for ACF.

Dated: December 18, 2007.

Brendan Kelly,

Reports Clearance Officer.

[FR Doc. 07–6158 Filed 12–21–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0472]

Agency Emergency Processing Under the Office of Management and Budget Review; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of December 12, 2007 (72 FR 70599). The document announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995. The document was published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning, and Preparedness (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION:IN FR DOC. 07–6023, APPEARING ON PAGE 70599 IN THE Federal Register OF WEDNESDAY, DECEMBER 12, 2007, THE FOLLOWING CORRECTION IS MADE: 1. On page 70599, in the third column, in the second full paragraph, the second sentence is corrected to read ''Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification that all applicable requirements of section 402(j) of the PHS Act have been met.''

Dated: December 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24914 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007C–0474]

DSM Nutritional Products, Inc.; Filing of Color Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of December 4, 2007 (72 FR 68166). The document announced that DSM Nutritional Products, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of astaxanthin dimethyldisuccinate as a color additive in the feed of salmonid fish to enhance the color of their flesh.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning, and Preparedness, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–23473, appearing on page 68166 in the **Federal Register** of Tuesday, December 4, 2007, the following correction is made:

1. On page 68166, in the third column, in the heading of the document, ''[Docket No. 2007N–0453]'' is corrected to read ''[Docket No. 2007C–0474]''.

Dated: December 17, 2007.

Laura M. Tarantino,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. E7–24911 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Trial Design for Community-Acquired Pneumonia; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA), regarding scientific issues in clinical trial design for community-acquired pneumonia. This public workshop is intended to provide information for and to gain perspective from health care providers, academia, and industry on various aspects of antimicrobial drug development for community-acquired pneumonia, including diagnosis of community-acquired pneumonia, effect of antimicrobial treatment for community-acquired pneumonia, endpoints for trials of community-acquired pneumonia, and statistical issues in analysis of results of trials in community-acquired pneumonia. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on January 17, 2008, from 8 a.m. to 6 p.m. and on January 18, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, Kennedy Room, 8777 Georgia Ave., Silver Spring, MD 20910, 301–589–0800. Seating is limited and available only on a first-come, first-served basis.

Contact Person: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Office of Antimicrobial Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6413, Silver Spring, MD 20993–0002, 301–796–0767, or 301–796–0849.

Registration: There is no registration fee for the public workshop. Space is limited; therefore, interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to *CAPwkshp@fda.hhs.gov* by January 9, 2008. Persons without access to the Internet can call 301–796–1300 to register. Persons needing a sign language interpreter or other special

accommodations should notify Chris Moser or Lori Benner (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA, regarding antimicrobial drug development. This public workshop will focus on scientific considerations in designing clinical trials for community-acquired pneumonia. The topics for discussion include approaches to the diagnosis of community-acquired pneumonia, the effect of antimicrobial treatment for community-acquired pneumonia, various endpoints that might be considered as endpoints for trials of community-acquired pneumonia, and statistical issues in analysis of results from trials in community-acquired pneumonia. The input from this public workshop will help in developing topics for further discussion.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 20 working days after the public workshop, at a cost of 10 cents per page.

Dated: December 18, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–24927 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0480]

Maximizing the Public Health Benefit of Adverse Event Collection Throughout a Product's Marketed Life Cycle; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA) are announcing a public workshop entitled ''Maximizing the Public Health Benefit of Adverse Event Collection Throughout a Product's Marketed Life Cycle.'' The purpose of the public workshop is to solicit information and views from interested persons on research approaches and methods associated with the best ways to assess the public health benefit of collecting and reporting all adverse events (AEs). The input from this workshop will be used to publish a request for information to determine the types of outside organizations that would be interested in, and have the capability to conduct, the research described in this paragraph, followed by a request for proposal (RFP).

DATES: The public workshop will be held on January 29, 2008, from 8:30 a.m. to 5 p.m. Individuals who wish to speak during the public workshop must register on or before January 15, 2008. See section III of this document for information on how to attend or present at the meeting.

We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by February 29, 2008.

ADDRESSES: The public workshop will be held at The Conference Facility (terrace level) located at 5635 Fishers Lane, Rockville, MD 20857 (Metro: Twinbrook Station on the Red Line).

Submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

FOR FURTHER INFORMATION CONTACT: Lana Pauls, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–0518, FAX: 301–827–1069, e-mail: *lana.pauls@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The collection of information relating to AEs is an integral part of understanding the safety of a product throughout its marketed life cycle. FDA is committed to maximizing the public health benefit of collecting and reporting serious and non-serious AEs. Central to addressing this question is determining the number and type of safety concerns discovered by AE collection, the age of products at the time safety concerns are detected by AE collection, and the types of actions that are subsequently taken to protect patient safety.

The workshop objectives are as follows: (1) Initiate constructive dialogue and information-sharing among regulators, researchers, the pharmaceutical industry, health organizations, and individuals affected by postmarketing AE collection, reporting, and evaluation; (2) share current FDA practices regarding postmarketing AE collection and reporting; and (3) obtain input on the questions and methods that will be used to conduct research on this topic.

Two panel discussions will focus on how FDA currently uses spontaneous reports and other methods of signal detection, the key research questions that should be addressed by the RFP, and appropriate research approaches and methods including, but not limited to, hypothesis, study design, data sources, outcome measures, and analytic methods. Panel one will focus on the key research questions; panel two will discuss research approaches and methods.

Some of the key questions to be addressed in the RFP include the following:

(1) What is the value to patient safety of collecting AEs through a passive surveillance system over the marketed life cycle of a product? How are these data best used in regulatory decision-making?

(2) How can safety issue identification and subsequent regulatory action be characterized in relation to time elapsed following product approval? Is this influenced by the type of regulatory action and/or the nature of the safety signal?

(3) What are the roles of serious and non-serious outcome reports in safety issue identification and subsequent regulatory action? How do the roles of