Company Superfund Site, Texas City, Galveston County, Texas, and EPA Docket Number 06–17–07, and should be addressed to Patrice Miller at the address listed above.

FOR FURTHER INFORMATION CONTACT: Anne Foster, 1445 Ross Avenue; Dallas, Texas 75202–2733 or call (214) 665–2169 or I-Jung Chiang, 1445 Ross Avenue, Dallas, Texas 75202–2733 or call (214) 665–2160.

Dated: December 14, 2009.

Al Armendariz,

Regional Administrator, Region 6.

[FR Doc. E9–30819 Filed 12–28–09; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Economic Analysis of Nutrition Interventions: Methods, Research and Policy

Notice

Notice is hereby given of the National Institutes of Health (NIH) Office of Dietary Supplements (ODS) Economic Analysis of Nutrition Interventions Workshop to be held February 23–24, 2010 at the Bethesda North Marriott Hotel & Conference Center in Bethesda, Maryland, 20852.

Summary

In 2008, healthcare expenditures in the U.S. were estimated to be 17% of GDP, and these projected expenditures were largely associated with chronic disease. Medicare beneficiaries spent a median of 16% of their incomes on healthcare, and if current trends persist, a family earning $60,000 ''gross wage base'' will be spending more than 41% of wages on healthcare in 10 years time. Despite the rapid escalation of healthcare costs, research into healthcare economic solutions has not taken center stage. Nutrition is a foundation of preventive medicine in our healthcare system, and it is postulated that better health outcomes can be achieved for dollars spent by ensuring proper nutrition of the population.

Health economic issues in the U.S. healthcare delivery system have gained increased prominence with President Obama's expressed desire to ''raise health care's quality and lower its costs.'' The National Institutes of Health Clinical and Translational Science Award Program has also recognized the importance of ''enhancing the adoption of best practices in the community,'' including assessment of the costs and effectiveness of prevention and treatment strategies. The potential benefits of health economic analysis applied to health policy include: identifying important factors affecting resource allocation in the setting of increasingly complex, uncertainty-laden medical detection and treatment advances; specifying a basis for allocating resources among diseases and in prevention versus detection, versus treatment; reminding decision-makers about the reality of limited resources; and, offering a rational approach to decision-making when resources are limited.

In view of the current interest in health economics and the potential societal benefit of incorporating health economics as a part of translational science, the NIH/ODS will host this day-and-a-half long workshop to bring together U.S. and international academicians, researchers, policymakers and regulators to address the following key areas and questions specifically as applied to nutrition interventions:

- *State of the Science:* What are the health economic methods currently used to judge burden of illness, interventions or healthcare policies, and what new research methodologies are available (or are needed, *i.e.* what are critical knowledge or methodological gaps or barriers?)
- *Research Applications:* What are the current and planned evidence-based health economic research activities in nutrition at the NIH, CDC, AHRQ, USDA, FDA, CMS, OMAR, etc. and what are the activities in other countries?
- *Regulatory and Policy Maker Perspectives:* Once these research goals have been met, how can they assist regulatory and policy makers with nutrition policy decision-making?

The workshop will consist of three half-day sessions which will cover the key areas identified above. Sessions will feature focused podium presentations, with each session concluding with a panel discussion. The workshop will conclude with a summary of the discussions, identification of knowledge gaps, and suggestions for future research initiatives.

The current sponsors of this meeting are the NIH Office of Dietary Supplements and the National Center for Complementary and Alternative Medicine.

Registration

Space is limited and will be filled on a first-come first-served basis. There is no registration fee to attend the workshop. To register please forward your name and complete mailing address, including phone number, via e-mail to Mr. Mike Bykowski at *mbykowski@csionweb.com.* Mr. Bykowski will be coordinating the registration for this meeting. If you wish to make an oral presentation during the meeting, you must indicate this when you register and submit the following information: (1) A brief written statement of the general nature of the comments that you wish to present, (2) the name and address of the person(s) who will give the presentation, and (3) the approximate length of time that you are requesting for your presentation. Depending on the number of people who register to make presentations, we may have to limit the time allotted for each presentation. If you do not have access to e-mail please call Mr. Bykowski at 301–670–0270.

Dated: December 18, 2009.

Paul M. Coates,

Director, Office of Dietary Supplements, National Institutes of Health.

[FR Doc. E9–30683 Filed 12–28–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0591]

Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions.'' This guidance describes the circumstances in which FDA will not object to certain compounding of Tamiflu Oral Suspension in advance of receiving prescriptions.

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

ADDRESSES: Submit written requests for single copies of this 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 that office in processing your

requests. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Samia Nasr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5370, Silver Spring, MD 20993–0002, 301–796–3409.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Guidance to Pharmacies on Advance Compounding of Tamiflu Oral Suspension to Provide for Multiple Prescriptions.'' The increasing prevalence of H1N1 infection and resultant increase in demand for Tamiflu for Oral Suspension has caused supply difficulties and spot shortages of the commercially manufactured Tamiflu for Oral Suspension product (12 milligrams (mg)/milliliter (mL)) throughout the country. Because of these shortages, compounding of Tamiflu Oral Suspension (15 mg/mL), as described in the FDA-approved labeling, can ensure that patients who have difficulty swallowing tablets have access to Tamiflu Oral Suspension when the commercially manufactured Tamiflu for Oral Suspension is unavailable.

This guidance describes the conditions in which FDA will not object to certain compounding of Tamiflu Oral Suspension (using Tamiflu capsules) in advance of receiving prescriptions. In circumstances where there is an actual shortage of commercially manufactured Tamiflu for Oral Suspension, FDA will not object if pharmacies compound oral suspension from Tamiflu capsules in advance of receiving prescriptions, if the amount compounded is commensurate with the number of valid prescriptions that the pharmacy can reasonably anticipate receiving within the next 24 hours.

In addition, the guidance provides detailed, step-by-step information for the preparation of pharmacy-compounded Tamiflu Oral Suspension (final concentration 15 mg/ml) from Tamiflu capsules in quantities that are based on patient weight. Information on proper storage and a dosing chart for pharmacy-compounded Tamiflu Oral Suspension are also provided.

This guidance is being issued as a Level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). It is being implemented immediately without prior public comment because of the shortage of the commercially manufactured Tamiflu for Oral Suspension and the potential hazard to the public health. However, the agency welcomes comments on the guidance and, if comments are submitted, the agency will review them and revise the guidance if appropriate. The guidance represents the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this document. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm188629.htm*.

Dated: December 23, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–30750 Filed 12–28–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[CMS–2474–NC]

Medicaid and CHIP Programs; Initial Core Set of Children's Healthcare Quality Measures for Voluntary Use by Medicaid and CHIP Programs

AGENCY: Office of the Secretary, HHS.

ACTION: Notice with comment period.

SUMMARY: This notice identifies and solicits public comments on the initial, recommended core set of children's health care quality measures for voluntary use by State programs administered under titles XIX and XXI of the Social Security Act, health insurance issuers and managed care entities that enter into contracts with Medicaid and Children's Health Insurance Programs, and providers of items and services under these programs, in accordance with the Children's Health Insurance Program Reauthorization Act of 2009 (Pub. L. 111–3). This notice also discusses steps already underway to facilitate the programs' voluntary use of the children's health care quality measures. In addition, this notice solicits comments on how the steps might be enhanced, and recommendations for additional steps to facilitate use of the measures.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 1, 2010.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of two ways (please choose only one of the ways listed):

1. *Electronic Mail. CHIPRAquality measures@ahrq.hhs.gov*.

2. *Regular Mail.* Agency for Healthcare Research and Quality, Attention: Office of Extramural Research, Education, and Priority Populations—Public Comment, CHIPRA Core Measures, 540 Gaither Rd., Rockville, MD 20850.

Please note that all submissions may be posted without change to *http://www.AHRQ.gov*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: *CHIPRAqualitymeasures@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On February 4, 2009, the Congress enacted the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3). Section 401(a) of the legislation amended the Social Security Act (the Act), to establish section 1139A (42 U.S.C. 1320b-9a). This section requires the Secretary to identify and publish for general comment an initial, recommended core set of child health quality measures for use by State programs administered under titles XIX and XXI of the Act, health insurance issuers and managed care entities that enter into contracts with such programs, and providers of items and services under such programs. The statute requires that the