

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.

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Dated: December 14, 2009.

Al Armedariz,

Regional Administrator, Region 6.

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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.

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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