Administration'' meeting information for September 16, 2008).

Currently the NTP is pursuing studies of absorption, distribution, metabolism, and excretion (ADME) in experimental animals (rodents and non human primates) as well as the kinetics associated with these processes, following exposures to BPA from the perinatal period through adulthood, over a wide range of doses, by multiple routes of administration. These studies have been identified as high priority needs in all recent reviews and reflect the general lack of information on concentrations of BPA in blood and target tissues in animal studies reporting effects of ''low'' doses of BPA on various aspects of development.

In addition to ADME studies, other areas of research have been suggested to better characterize possible hazards associated with BPA exposures in humans. They include studies to (1) Examine pathways of human exposures, (2) identify cellular targets for BPA at low and high doses for consistency with an estrogenic mechanism of action, (3) identify interactions with other estrogenic substances including naturally occurring hormones, and (4) investigate further the ''low'' dose effects reported in experimental animals.

The findings from the ADME studies and the information collected as a result of this RFI will be analyzed and considered for use in the further development of NTP and NIEHS/DERT research and testing programs on BPA.

Information Requested

The NTP and NIEHS/DERT request information on the following:

- Ongoing or planned research activities that you are aware of related to this RFI.
- Specific data needs for any or all of the priority areas identified below.
- Suggestions for beneficial research collaborations.

To aid in the development of a listing of prioritized data needs, a summary listing of the research needs identified in the NTP CERHR evaluation, the NIEHS co-sponsored workshop, or the draft FDA assessment are included below. This list may be used as a starting point for developing a prioritized listing of research needs related to the health effects of BPA.

1. Studies of the concentrations of BPA and metabolites in human blood, urine, breast milk, amniotic fluid, placenta and other tissues, particularly in infants and young children, where appropriate.

2. More complete assessment of sources of human exposure to BPA.

3. *In vitro* studies examining interactions of BPA with multiple cellular targets (toxicity pathways) across a range of concentrations, and comparing these results with similar studies of other known estrogenic agents and combinations of estrogenic agents with BPA.

4. Studies of gestational and lactational exposure of experimental animals to ''low'' doses of BPA regarding effects on development and onset of adult disease including:

a. The sensitivity of the developing brain to BPA induced structural, functional, and biochemical alterations.

b. The relevance to primates of diminished estrogen-dependent brain and behavioral sexual dimorphisms in rodents exposed to BPA during development.

c. Confirmation of rodent studies reporting behavioral effects following BPA exposure during development related to the dopaminergic systems such as novelty-seeking, socio-sexual behaviors, and response to addictive drugs.

d. The susceptibility of the mammary gland and prostate gland to alterations in development from exposures to BPA.

e. The predilection of BPA-induced changes in mammary gland and prostate gland development to neoplasia later in life.

5. The robustness and biologic basis for altered puberty following BPA exposure in multiple species.

6. The potential for effects on the immune system.

7. The potential for metabolic disruptions leading to obesity, diabetes, or other metabolic diseases.

8. The potential for disruptions to the male reproductive tract including effects on sperm quantity and quality.

9. The potential for aneuploidy or chromosomal disruption to female germ cells and for proliferative and/or cystic changes to the ovary and uterus later in life.

10. Other areas not previously identified.

All responses to information requested within this RFI are optional. The information collected will be analyzed and considered for use in the further development of NTP and NIEHS/DERT research and testing programs on BPA. The summarized data (without identifiers) may appear in future reports. Although the NIH will provide safeguards to prevent the release of identifying information there is no guarantee of confidentiality. This RFI is for planning purposes and shall not be construed as a solicitation for applications nor as an obligation on the part of the Government. The Government will not pay for the preparation of any information submitted or for the Government's use of that information. Respondents will not be notified of the Government's assessment of the information received. No basis for claims against the Government shall arise as a result of responses to this RFI, or in the Government's use of such information as part of its evaluation process.

Dated: October 7, 2008.

Samuel H. Wilson,

Acting Director, National Institute of Environmental Health Sciences and National Toxicology Program.

[FR Doc. E8–25053 Filed 10–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 73 FR 46300–46301, dated August 8, 2008) is amended to reflect the reorganization of the Coordinating Center for Infectious Diseases at the Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the functional statement for the *Strategic Business Unit (CVA2)* and insert the following:

Strategic Business Unit (CVA2). The mission of the Strategic Business Unit (SBU) is to support CCID programs and staff through the efficient, professional, and timely delivery of critical public health mission-support services. In carrying out its mission, the SBU performs the following functions: (1) Provides direct and daily management and execution of domestic travel processing for federal employees, Commissioned Corps, and all CDC-invited guests; (2) provides direct and daily management and execution of the administrative aspects of human resources across CCTD, including training and administration of policies and guidelines developed by the Atlanta Human Resources Center, Department of Health and Human Services (HHS),

Ethics Office, Financial Management Office (FMO), Office of Commissioned Corps Personnel, Coordinating Office for Global Health (COGH), Office of Personnel Management, Office of Workforce and Career Development, and Procurement and Grants Office (PGO); (3) provides direct and daily management and execution of the coordination of laboratory and office facilities, and supplies technical guidance and expertise regarding occupancy and facilities management to emergency situations, CDC; (4) provides direct and daily management and execution of the distribution, accountability, and maintenance of CDC property and equipment; (5) provides direct and daily management and execution of micro purchases and procurement requisitions, and performs administrative tasks related to initiating, processing and maintaining interagency agreements; and provides training and administration of policies and procedures developed by PGO and FMO regarding acquisitions; 6) provides direct and daily management and execution of the creation, organization, access, maintenance, and disposition of CCID records, and of the establishment of policies and procedures coordinating a CCID response to Freedom of Information Act (FOIA) requests; and (7) provides direct and daily management and execution of the coordination of logistics for CCID's federal government committee meetings and conferences.

Delete in their entirety the titles and functional statements for the following:

Travel (CVA22), Personnel/Training (CVA23), Procurement/Property/ Facilities (CVA24), and Records Management/FOIA/Committee Management/Conference Logistics (CVA25).

Dated: October 8, 2008.

William H. Gimson,

Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. E8–24812 Filed 10–20–08; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0170]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification for a New Dietary Ingredient'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 19, 2008 (73 FR 34940), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0330. The approval expires on August 31, 2011. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: October 14, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–25091 Filed 10–20–08; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0548]

Authorization of Emergency Use of Doxycycline Hyclate Tablet Emergency Kits for Eligible United States Postal Service Participants in the Cities Readiness Initiative and Their Household Members; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for doxycycline hyclate tablet emergency kits for eligible United States Postal Service (USPS) participants in the Cities Readiness Initiative (CRI) and their household members. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, HHS. The Authorization contains, among other things, conditions on the emergency use of doxycycline hyclate tablet emergency kits. The Authorization follows the determination by the Secretary of the Department of Homeland Security that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*. On the basis of such determination, Secretary of Health and Human Services Michael O. Leavitt (the Secretary) declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). The Authorization, which includes an explanation of the reasons for its issuance, is reprinted in this Notice.

DATES: The Authorization is effective as of October 3, 2008.

ADDRESSES: Submit written requests for single copies of the Emergency Use Authorization to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane (HF–29), rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a domestic emergency, or a significant