Zantac® business to Boehringer Ingelheim Pharmaceuticals by requiring that: (1) J&J divest to Boehringer Ingelheim Pharmaceuticals all assets relating to Pfizer's Zantac® line of products, including all research and development, intellectual property, and customer and supply contracts; (2) J&J and Pfizer take steps to ensure that confidential business information relating to Zantac® will not be obtained or used by J&J; (3) Boehringer Ingelheim Pharmaceuticals have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Zantac®; and (4) certain management employees of Pfizer who were substantially involved in the research, development or marketing of Zantac® be precluded from working on competitive H–2 blocker products at J&J for a period of two years.[2]

The Commission is also satisfied that Chattem is a well-qualified acquirer of the Cortisone®, Unisom®, and Balmex® businesses. Chattem is a leading manufacturer and marketer of a broad portfolio of branded OTC healthcare products, toiletries, and dietary supplements, including brands such as Icy Hot®, Gold Bond®, Selsun blue®, Garlique®, Pamprin®, and BullFrog®. Chattem's products are among the market leaders in their respective categories across food, drug and mass merchandisers. Chattem has an experienced sales force with existing relationships with major retailers and has a strong record of integrating prior product acquisitions successfully.

The proposed Consent Agreement contains several provisions designed to ensure the successful divestiture of the Cortisone®, Unisom®, and Balmex® businesses to Chattem by requiring that: (1) J&J divest to Chattem all assets relating to the Cortisone®, Unisom®, and Balmex® line of products, including all research and development, intellectual property, and customer and supply contracts; (2) J&J and Pfizer take steps to ensure that confidential business information relating to Cortisone®, Unisom®, and Balmex® will not be obtained or used by J&J; and (3) Chattem have the opportunity to enter into employment contracts with certain key individuals who have experience relating to Cortisone®, Unisom®, and Balmex®.

The Order to Maintain Assets that is included in the proposed Consent Agreement requires that J&J and Pfizer maintain the viability of the Divested Assets for the brief transition period between the time the Commission approves the proposed Order and when the divestitures take place, which will not be later than January 2, 2007. Even though such a period is relatively short, maintenance of current supply, advertising and promotional levels and activities at all times prior to divestiture is of paramount importance. The proposed Consent Agreement incorporates this plan in the Order to Maintain Assets, detailing requirements for the assets that must be held separate, services that may be shared with the ongoing business, and the employee positions that are necessary for the held separate business.

The Commission has appointed David Painter of LECG as Interim Monitor to oversee the transfer of assets, the establishment of appropriate firewalls to prevent the transfer or use of confidential business information and to ensure that J&J and Pfizer comply with all other provisions of the Order. To ensure that the Commission remains informed about the status of the Divested Assets and their transfer, the proposed Consent Agreement requires J&J and Pfizer to file reports with the Commission periodically until the divestitures are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

By direction of the Commission with Commissioners Harbour, Kovacic and Rosch recused.

Donald S. Clark,

Secretary.

[FR Doc. E6–21519 Filed 12–15–06; 8:45 am]

BILLING CODE 6750–01–P

[2] This firewall will prevent J&J from taking competitive advantage of know-how, product development, marketing, and sales plans relating to Zantac®.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–07–07AA]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Pilot Project for a National Monitoring System for Major Adverse Effects of Medication Use During Pregnancy and Lactation—New—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This data collection is based on the following components of the Public Health Service Act: (1) Act 42 U.S.C. 241, Section 301, which authorizes ''research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man.'' (2) 42 U.S.C. 247b–4, Section 317 C, which authorizes the activities of the National Center on Birth Defects and Developmental Disabilities. This section was created by Public Law 106–310, also known as ''the Children's Health Act of 2000.'' This portion of the code has also been amended by Public Law 108–154, which is also known as the ''Birth Defects and Developmental Disabilities Prevention Act of 2003''.

The use of a number of medications during pregnancy is known to be associated with serious adverse effects in children. However, because pregnant and lactating women are traditionally excluded from clinical trials, and because premarketing animal studies do not necessarily predict the experience of humans, little information is available about the safety of most prescription

medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not have a comprehensive early warning system for major adverse pregnancy or infant outcomes related to medication exposures.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the adverse effects of medication exposures during pregnancy and lactation. The objective of this project is to conduct a pilot study to assess whether TIS in the United States can serve as an effective monitoring and early warning system for major adverse effects on (1) pregnancy outcomes (e.g., live birth, stillbirth, premature birth, low birth weight, etc.) and (2) maternal and infant health. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about adverse pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (approximately 250 enrollees per TIS) who have used any prescription or over-the-counter medication during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will conduct 4 telephone interviews:(1) At enrollment; (2) during the third trimester of pregnancy; (3) approximately one month after delivery; and (4) when the infant is about 3 months old. For each breastfeeding woman who agrees to participate, the TIS will conduct 3 telephone interviews:(1) At enrollment; (2) approximately one month after enrollment; and (3) 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, and maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondent	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
Prenatal exposure group alone	338	4	20/60	451
Lactation exposure group alone	74	3	20/60	74
Prenatal exposure group and lactation exposure group (pregnant women who subsequently breastfeed)	338	4	30/60	676
Total	750			1,201

Dated: December 12, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–21527 Filed 12–15–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0246]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

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 January 17, 2007.

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: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Manufactured Food Regulatory Program Standards

The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Manufactured Food Regulatory Program Standards: (draft program standards). The draft program standards, which establish a uniform foundation for the design and management of State programs responsible for regulation of plants that manufacture, process, pack, or hold foods in the United States, are being distributed for comment purposed only. This document is neither final nor is it intended for implementation.

The elements of the draft program standards are intended to ensure that the States have the best practices of a high-quality regulatory program to use for self-assessment and continuous improvement and innovation. The ten standards describe the critical elements