1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Margaret Kober, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4243.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms—Prescribing Information for Health Care Providers and Patient Labeling.'' The draft guidance describes the recommended labeling for health care providers and patient instructions for inclusion in new drug applications (NDAs). A draft of this guidance was first issued in September 1999 (64 FR 52100). However, on September 10, 2002, the agency withdrew the draft guidance (67 FR 57432), pending consideration of the results from the National Institutes of Health (NIH) Women's Health Initiative (WHI).[1] This second draft reflects the agency's thinking after considering the results of the WHI substudy.

In the WHI substudy, postmenopausal women who took conjugated estrogen 0.625 milligram (mg) combined with medroxyprogesterone acetate 2.5 mg had higher risks of several serious adverse events relative to those women who took placebo. Conjugated estrogens alone also increased the rates of cardiovascular disease compared to placebo. Other doses of conjugated estrogens and medroxyprogesterone acetate and other combinations of estrogens and progestins were not studied in the WHI. However, in the absence of comparable data, the risks of serious adverse events should be assumed to be similar because other studies show that estrogens and progestins are associated with these types of events.

This second draft of the guidance reflects several changes. For example, the draft guidance provides specific labeling recommendations for two indications (moderate to severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy). It refers sponsors to the appropriate review divisions for guidance on labeling products to treat other indications. In addition, the guidance recommends that the following additions be made to the labeling for noncontraceptive estrogen drug products for the treatment of vasomotor symptoms and symptoms of vulvar and vaginal atrophy:

- New information to the boxed warning;
- Information from the WHI, including a statement that, although only a single dose and type of estrogen and progestin were studied in the WHI, risks for serious adverse events should be assumed to be similar for other estrogens and progestins until data show otherwise;
- A statement recommending that use of estrogens should be at the lowest doses and for the shortest duration in hopes of minimizing risks;
- A revised indication for the treatment of vulvar and vaginal atrophy in women who have moderate to severe symptoms so that benefits from drug therapy may outweigh risks; and
- Information from the WHI on cardiovascular and cancer risks as well as other information from the WHI and other studies.

Finally, the new draft updates other information in the label based on current scientific studies.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on labeling for noncontraceptive estrogen drug products for the treatment of vasomotor symptoms and vulvar and vaginal atrophy symptoms. 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch 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 either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: January 23, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2377 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

[1] The results of the NIH Women's Health Initiative trial were reported in the *Journal of the American Medical Association*, 288: 321–333, 2002.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0001]

Draft Guidance for Industry on Nonclinical Safety Evaluation of Pediatric Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients.

DATES: Submit written or electronic comments on the draft guidance by May 5, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Davis Bruno, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600

Fishers Lane, Rockville, MD 20857, 301–827–6430.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. In most cases to date, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some drug effects also may be difficult to detect in clinical trial or during routine postmarketing surveillance.

The draft guidance provides recommendations on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It describes how juvenile animal studies can be useful in monitoring, timing, and phasing of trials for initial enrollment in pediatric clinical studies. The draft guidance is intended to serve as a resource for general considerations in animal testing and to provide recommendations based on the available science and pragmatic considerations. The scope of animal studies is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' 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 Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Managment Branch 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 either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: January 21, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2376 Filed 1–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: SAMHSA/HRSA Collaboration to Link Health Care for the Homeless Programs and Community Mental Health Agencies—(New)—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Mental Health Services (CMHS); the Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC); and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) propose to conduct a longitudinal, multi-site evaluation assessing their initiative to foster collaborations between Health Care for the Homeless programs (HCH) and community mental health agencies (CMHA). In 12 designated communities, an HCH site and a CMHA site will collaborate to increase the availability of mental health and primary care services for persons with serious mental illness and co-occurring substance use disorders who are homeless. The evaluation of these collaborative efforts will advance knowledge on elements of the implementation process associated with establishment of a successful collaboration, such as partnering mechanisms, success of referral links, intensity of services, the effects of collaboration on client outcomes, and plans for sustainability.

Data collection will be conducted over a 30-month period. In each community, both a process and an outcome evaluation will be conducted to address the following questions: How is the project being implemented? What are the identified collaboration mechanisms? What are the service/agency level outcomes? What are the system-level outcomes? What are the client-level outcomes? To what extent do the various collaboration strategies predict outcomes?

To reduce burden and increase uniformity across the study sites, a common case study protocol will be used to guide the evaluation. Information for the service/agency and system level evaluations will be collected by staff from the central Evaluation Center (EC) during annual site visits and through activity logs. Common site visit protocols will dictate what data collection methods will be used. Site visitors will rely on focus groups and interviews to obtain information from project directors, local evaluators, project staff, and clients. Activity logs monitoring each community's efforts to implement collaboration strategies, will be completed by program administrators and submitted to the EC quarterly. Key outcomes to be examined at the service/agency level through these data collection methods include increased availability of mental health, substance abuse, specialty care, housing and services; increased access to primary care, mental health, and substance abuse services; more comprehensive assessment of and services for individual needs; increased integrated delivery of services; and increased engagement and retention in services. System-level outcomes to be examined include increased cross-agency activity;