withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

FDA regulations provide that any person may petition the agency for a determination as to whether a listed drug has been voluntarily withdrawn from sale for reasons of safety effectiveness (§ 314.161(b) (21 CFR 314.161(b))). Richard A. Hamer submitted a citizen petition dated May 24, 1996, under 21 CFR 10.25(a), 10.30, and 314.122(a), requesting that the agency determine whether chlorhexidine gluconate topical tincture 0.5% (Hibitane®) was withdrawn from sale for reasons of safety or effectiveness. Zeneca Pharmaceuticals (formerly Steuart Pharmaceuticals and ICI Americas) obtained approval of NDA 18–049 for chlorhexidine gluconate topical tincture 0.5% on December 18, 1978, as a patient preoperative skin preparation. The product was withdrawn from sale by the sponsor in early 1984. Because the sponsor discontinued marketing of the product, the agency currently lists chlorhexidine gluconate topical tincture 0.5% in the Orange Book's ''Discontinued Drug Product List.''

FDA has reviewed its records and, under §§ 314.161 and 314.162(a)(2), has determined that chlorhexidine gluconate topical tincture 0.5% was withdrawn from sale for reasons of safety. Specifically, the product was withdrawn because of the significant number of reports received concerning chemical and thermal burns associated with the use of the product. Therefore, chlorhexidine gluconate topical tincture 0.5% will be removed from the list of drug products with effective approvals published in FDA's publication, ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' FDA will not accept ANDA's that refer to this drug product.

Dated: September 26, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26353 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0410]

Guidance for Industry on SUPAC–MR, Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes for Chemistry, Manufacturing, and Controls; 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 ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic applications (AADA's) who intend to change the components or composition, the manufacturing (process or equipment), the scale-up/scale-down of manufacture, and/or the site of manufacture of a modified release solid oral formulation during the postapproval period. This guidance document represents the agency's current thinking on scale-up and postapproval changes (SUPAC) for modified release solid oral dosage forms regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mehul U. Mehta, Center for Drug Evaluation and Research (HFD–860), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–0501.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''SUPAC–MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of NDA's, ANDA's, and AADA's who intend to change: (1) The components or composition; (2) the manufacturing (process or equipment); (3) the scale-up/scale-down of manufacture; and/or (4) the site of manufacture of a modified release solid oral formulation during the postapproval period. The guidance document defines the following: (1) Levels of change; (2) recommended chemistry, manufacturing, and controls (CMC) tests to support each level of change; (3) recommended in vitro dissolution release tests and/or in vivo bioequivalence tests to support each level of change; and (4) documentation to support the change.

For postapproval changes for modified release dosage forms that affect components and composition, manufacturing process or equipment changes, scale-up, and site change, this guidance supersedes the recommendations in section 4.G of the *Office of Generic Drugs Policy and Procedure Guide 22–90* (FDA, September 11, 1990). For all other dosage forms and changes, this guidance does not affect the recommendations in *Guide 22–90*.

This guidance document represents the agency's current thinking on SUPAC for modified release solid oral dosage forms regulated by CDER. 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance

document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guidance is also available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

Dated: September 29, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26412 Filed 10–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Estimation Methodology for Children With a Serious Emotional Disturbance (SED)

AGENCY: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Solicitation of comments.

SUMMARY: This notice describes the proposed methodology for identifying and estimating the number of children with a serious emotional disturbance (SED) within each State. This notice is being served as part of the requirement of Public Law 102–321, the ADAMHA Reorganization Act of 1992.

COMMENT PERIOD: The Administrator is requesting written comments which must be received on or before December 5, 1997.

ADDRESSES: Comments should be sent to Judith Katz-Leavy, M.Ed., Senior Policy Analyst, Office of Policy, Planning, and Administration, Center for Mental Health Services, Parklawn Building Room 15–87, 5600 Fishers Lane, Rockville, MD 20857. (301) 443–1563 fax.

FOR FURTHER INFORMATION CONTACT: A detailed paper outlining the estimation methodology described here is available from: Judith Katz-Leavy M.Ed., Senior Policy Analyst, Office of Policy, Planning, and Administration, Center for Mental Health Services, Parklawn Building Room 15–87, 5600 Fishers Lane, Rockville, MD 20857. (301)443–1563 fax.

Background

Public Law 102–321, the ADAMHA Reorganization Act of 1992, amended the Public Health Service Act and created the Substance Abuse and Mental Health Services Administration (SAMHSA). The Center for Mental Health Services (CMHS) was established within SAMHSA to coordinate Federal efforts in the prevention, treatment, and promotion of mental health. Title II of Public Law 102–321 establishes a Block Grant for Community Mental Health Services (Block Grant) administered by CMHS, which permits the allocation of funds to States for the provision of community mental health services to children with a serious emotional disturbance and adults with a serious mental illness. Public Law 102–321 stipulates that States estimate the incidence (number of new cases) and prevalence (total number of cases in a year) in their applications for Block Grant funds, see 42 U.S.C. 300 (2). The statute also requires the Secretary to establish definitions for adults with a serious mental illness and children with a serious emotional disturbance. In addition, the Secretary is required to develop standardized methods for the states to use in providing the estimates required as part of their block grant applications. See 42 U.S.C. 300 (2). As part of the process of implementing this new block grant, definitions of the terms ''children with a serious emotional disturbance'' and ''adults with a serious mental illness'' were announced on May 20, 1993, in **Federal Register** Volume 58, No 96, p. 29422. Subsequently, a group of technical experts was convened by CMHS to develop an estimation methodology to ''operationalize the key concepts'' in the definition of children with a serious emotional disturbance. A similar group has prepared an estimation methodology for adults with a serious mental illness.

Serious Emotional Disturbance (SED)

The CMHS definition is that ''children with serious emotional disturbance'' are persons:

—From birth up to age 18;
—Who currently or at any time during the past year;
—Have had a diagnosable mental, behavioral, or emotional disorder of sufficient duration to meet diagnostic criteria specified within DSM–III–R
—That resulted in functional impairment which substantially interferes with or limits the child's role or functioning in family, school, or community activities (p.29425).

The definition goes on to indicate that, ''these disorders include any mental disorder (including those of biological etiology) listed in DSM–III–R or their ICD–9–CM equivalent (and subsequent revisions) with the exception of DSM–III–R 'V' codes, substance use, and developmental disorders, which are excluded, unless they co-occur with another diagnosable serious emotional disturbance'' (p. 29425).

Further, the definition indicates that, ''Functional impairment is defined as difficulties that substantially interfere with or limit a child or adolescent from achieving or maintaining one or more developmentally-appropriate social, behavioral, cognitive, communicative, or adaptive skills. Functional impairments of episodic, recurrent, and continuous duration are included unless they are temporary and expected responses to stressful events in their environment. Children who would have met functional impairment criteria during the referenced year without the benefit of treatment or other support services are included in this definition'' (p. 29425).

The first decision that was made was to focus on community epidemiological studies done in the United States that used either the DSM–III–R, or its predecessor, the DSM–III, and that provided information on the prevalence of mental disorders using a structured interview procedure. The group decided that given the relatively small number of community epidemiological studies that had been conducted in the United States, it would be a mistake to exclude those few studies that had used the DSM–III, given its considerable similarity to the DSM–III–R.

The most frequently used structured interview procedure was the Diagnostic Interview Schedule for Children (DISC), originally developed by A. Costello and his colleagues (A. Costello, Edelbrock, Dulcan, Kalas, & Klaric, l984), which includes both child and parent versions. Other interview procedures include the Diagnostic Interview for Children and Adolescents (DICA, Herjanic & Reich, l982), the Child and Adolescent Psychiatric Assessment (CAPA, Angold & E. Costello, l995), and the Composite International Diagnostic Interview (CIDI, Kessler et al, 1994).

The group elected to consider that a child met the criteria of a diagnosable disorder either if a diagnosis was obtained from his/her own report on the structured interview, or from the parent's report on the structured interview, or from the combination of the youth's report and the parent's report, even if neither one met the criteria separately. While there are other approaches to combining data from two or more sources that were considered and have been used (Cohen, Velez, & Kohn, l987; Reich & Earls, 1987), the group chose to use this ''either/or'' approach because it was believed that