once, during the 6-month post-discharge interview. The CMHS–W contains eight questions, and six items are common between the men and women's versions of the instrument.

Correctional Mental Health Screener for Men

A mental health screener for men (CMHS–M) will be administered to gather data on drug court participants' mental health. Many drug court clients have co-occurring disorders (*i.e.,* substance use and mental health disorders). The information gathered during this portion of the in-person drug court client interviews will provide a post-discharge indicator of mental health status and will be used as a moderator variable when assessing client outcomes such as drug use and arrest. This questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview. The CMHS–M contains twelve questions and the two instruments have six items in common.

Treatment Satisfaction Index

The Treatment Satisfaction Index will ask drug court participants about their satisfaction with treatment received during the drug court program. This 19-item questionnaire will be administered to drug court participants once, during the 6-month post-discharge interview.

The estimated response burden for this data collection is provided in the table below:

ANNUALIZED ESTIMATES OF HOUR BURDEN

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Drug Court Team Questionnaire	240	3	720	.5	120
Drug Court Clients Focus Group Questions for Guided Discussion	600	1	600	1.0	600
Drug Court Clients—Interviews	816	1	816	.5	408
Procedural Justice Questionnaire	816	1	816	.09	73
Correctional Mental Health Screener—Women	408	1	408	.08	33
Correctional Mental Health Screener—Men	408	1	408	.08	33
Treatment Satisfaction Index	816	1	816	.08	65
Total	1,656	.....	2,136	.....	1,128

The estimates in this table reflect the maximum burden for participation in the Adult Treatment Drug Court Cross-Site Evaluation. Burden for drug court personnel is aggregated to reflect total burden over the three-year study period. The drug court personnel questionnaire will be administered three times; once during each of three study years. Burden for the drug court clients is annualized. Focus groups and interviews are one-time events. Some drug court clients will participate in both a focus group and 6-month post-discharge interview.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: April 13, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–9072 Filed 4–20–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Developmental Disabilities Council 5-Year State Plan.

OMB No.: 0980–0162.

Description: A Plan developed by the State Council on Developmental Disabilities is required by federal statute. Each State Council on Developmental Disabilities must develop the plan, provide for public comments in the State, provide for approval by the State's Governor, and finally submit the plan on a five-year basis. On an annual basis, the Council must review the plan and make any amendments. The State Plan will be used (1) By the Council as a planning document; (2) by the citizenry of the State as a mechanism for commenting on the plans of the Council; and (3) by the Department as a stewardship tool, for ensuring compliance with the Developmental Disabilities Assistance and Bill of Rights Act, as one basis for providing technical assistance (e.g., during site visits), and as a support for management decision making.

Respondents: State Govenments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Developmental Disabilities Council 5-Year State Plan	55	1	367	20,185

Estimated Total Annual Burden Hours: 20,185.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it

within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: April 16, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–9106 Filed 4–20–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0031] (formerly Docket No. 2007D–0233)

Guidance for Industry on Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document; 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 ''Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.'' Since FDA began accepting new drug application (NDA) and biologics license application (BLA) submissions in the common technical document (CTD) format, there has been confusion regarding where within the CTD to include an integrated summary of effectiveness (ISE) and integrated summary of safety (ISS), both of which are required components of an NDA submission and recommended components of a BLA submission. This guidance informs applicants where to place the ISE and ISS in the CTD, addresses specific FDA requirements not discussed in the ICH guidance for industry ''M4E: The CTD—Efficacy,'' and is intended to improve application quality and consistency. This guidance finalizes the draft guidance of the same title published in the **Federal Register** of July 3, 2007 (72 FR 36471).

DATES: Submit written or electronic 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; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Howard Chazin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6470, Silver Spring, MD 20993–0002, 301–796–0700; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.'' This guidance is intended for applicants submitting an NDA or BLA in the CTD or electronic common technical document (eCTD) format. Since FDA adopted the CTD, a standard way to organize a marketing or licensing application, there has been confusion regarding where to place an ISE and ISS within the CTD. The ISE and ISS are unique requirements of the United States and are not addressed fully by ICH M4E.

FDA considers the ISE and ISS critical components of the clinical efficacy and safety portions of a marketing or licensing application. Therefore, the ISE and ISS are required in NDA applications submitted to FDA in accordance with the regulations in 21 CFR 314.50(d)(5)(v) and (d)(5)(vi)(a). Although there are no corresponding regulations requiring an ISE or ISS for BLAs, applicants are encouraged to provide these analyses.

A common problem with the way many of the CTD-formatted applications are submitted is that applicants incorrectly assume that the clinical summaries in Module 2 satisfy the regulatory requirements for the ISE and ISS. This assumption can result in a determination by FDA that an application is incomplete. Despite their names, the ISE and ISS are detailed integrated analyses of all relevant data from the clinical study reports, not summaries. This guidance focuses on where to place ISE and ISS documents within the structure of the CTD or eCTD.

This guidance updates the part of sections II.G. and H. of the guidance on the ''Format and Content of the Clinical and Statistical Sections of an Application'' that relates to placement of the ISE and ISS. This guidance finalizes the draft guidance of the same title that published in the **Federal Register** of July 3, 2007 (72 FR 36471). No public comments were received regarding the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the location for an ISE and ISS within the CTD. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management 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 *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: April 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9051 Filed 4–20–09; 8:45 am]

BILLING CODE 4160–01–S