topics. The workshop provided valuable information, but additional time was needed at the close of the meeting for continued dialogue on important topics. At the end of the workshop, we invited written comments to provide an opportunity for a full discussion of issues.

We have established this docket to encourage interested parties to continue to provide information about Factor VIII inhibitors, comments on the workshop, and comments on information submitted to the docket by other interested parties. We also request that those who have already submitted written comments and information to FDA resubmit the same comments to the docket to ensure their adequate consideration since this information was not previously submitted to the docket. We also posted this request for comments and information at *http://www.fda.gov/cber/meetings/fctrvIII112103L.htm*.

Comments submitted to the docket will assist us in determining the need for and feasibility of establishing new inhibitor assay standards and methodologies, stakeholders' opinions about current upper and lower limits of acceptable inhibitor formation in clinical trials, and the use of plasma-derived versus recombinant Factor VIII controls in pharmacokinetic trials, among other issues. We may also consider the information in preparing any future guidance on clinical trials to evaluate potential inhibitor formation from Factor VIII products.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the workshop. 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. A copy of this notice, the slide presentations and transcript from the workshop, and received comments are available for public examination 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 slide presentations at *http://www.fda.gov/cber/summaries.htm* and the transcript of the workshop at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: June 24, 2004.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15135 Filed 7–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1981N–0033P]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Antigingivitis/Antiplaque Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following condition as part of FDA's ongoing review of over-the-counter (OTC) drug products: Triclosan, 0.3 percent maximum, as an antigingivitis ingredient in dental pastes and oral rinses. FDA has reviewed a time and extent application (TEA) for this condition and determined that it is eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether this condition can be generally recognized as safe and effective (GRAS/E) for its proposed OTC use.

DATES: Submit data, information, and general comments by October 4, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term ''condition'' means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that the agency reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5 U.S.C. 552(b), or 21 U.S.C. 331(j) was deleted from the TEA before it was placed on public display.

II. Request for Data and Information

The condition triclosan, 0.3 percent maximum, as an antigingivitis ingredient in dental pastes and oral rinses will be evaluated for inclusion in the monograph being developed for OTC oral health care drug products (21 CFR part 356). FDA will include this condition in its review of antigingivitis/antiplaque drug products. FDA published the advance notice of proposed rulemaking for these products in the **Federal Register** of May 29, 2003 (68 FR 32232). FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of this active ingredient for this use, so that FDA can determine whether it can be GRAS/E and not misbranded under recommended conditions of OTC use.

Interested persons should, on or before 90 days after the date of publication in the **Federal Register**, submit comments, data, and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments, data, and information are to

be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. Marketing Policy

Under § 330.14(h), any product containing the condition for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for triclosan as an antigingivitis active ingredient submitted by CIBA Specialty Chemicals Corp. on November 25, 2003.

2. FDA's evaluation and comments on the TEA for triclosan.

Dated: June 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–15136 Filed 7–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

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

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301–443–6014 (voice), 301–443–3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.

To maintain that certification, a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines, the following laboratories meet the minimum standards set forth in the Mandatory Guidelines:

ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840 / 800–877–7016 (Formerly: Bayshore Clinical Laboratory);

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585–429–2264;

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118, 901–794–5770 / 888–290–1150;

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400;

Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center);

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917;

Diagnostic Services Inc., dba DSI, 12700 Westlinks Dr., Fort Myers, FL 33913, 239–561–8200 / 800–735–5416;

Doctors Laboratory, Inc.,** 2906 Julia Drive, Valdosta, GA 31602, 229–671–2281;

DrugProof, Division of Dynacare/ Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2661 / 800–898–0180 (Formerly: Laboratory of Pathology of Seattle, Inc., DrugProof, Division of Laboratory of Pathology of Seattle, Inc.);

DrugScan, Inc., P.O. Box 2969, 1119 Mearns Rd., Warminster, PA 18974, 215–674–9310;

Dynacare Kasper Medical Laboratories,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2, 780–451–3702 / 800–661–9876;

ElSohly Laboratories, Inc., 5 Industrial Park Dr., Oxford, MS 38655, 662–236–2609;

Express Analytical Labs, 3405 7th Ave., Suite 106, Marion, IA 52302, 319–377–0500;

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall St., London, ONT, Canada N6A 1P4, 519–679–1630.

General Medical Laboratories, 36 South Brooks St., Madison, WI 53715, 608–267–6225;

Kroll Laboratory Specialists, Inc., 1111 Newton St., Gretna, LA 70053, 504–361–8989 / 800–433–3823 (Formerly: Laboratory Specialists, Inc.);

LabOne, Inc., 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927 / 800–873–8845 (Formerly: Center for Laboratory Services, a Division of LabOne, Inc.);

Laboratory Corporation of America Holdings, 7207 N. Gessner Rd., Houston, TX 77040, 713–856–8288 / 800–800–2387;

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400 / 800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.);

Laboratory Corporation of America Holdings, 1904 Alexander Dr.,