

during site visits), and as a support for management decision making.

Respondents: 55 State Developmental Disabilities Councils.

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:* 202-395-7285. *E-mail:* oir_submission@omb.eop.gov, *Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2011-13416 Filed 5-31-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0305]

Draft Guidance for Industry and FDA Staff: Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance

entitled "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." This draft guidance document is intended for manufacturers and distributors of research use only (RUO) and investigational use only (IUO) in vitro diagnostic (IVD) products and any other entities who label IVD products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 30, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "Commercially Distributed in Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993 or Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft 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>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Tonya Wilbon, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 5663, Silver Spring, MD 20993-0002, 301-796-6224.

FOR QUESTIONS RELATING TO DEVICES REGULATED BY CBER, CONTACT: Stephen

Ripley (HFM-17), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

RUO and IUO IVD products are distinctive in that they are devices that may themselves be used in research or investigations on human samples that may eventually lead to their clearance or approval for clinical diagnostic use, and they also may be marketed for and used in the research and investigation of other FDA-regulated products. Thus, the manufacturer of an IUO IVD product is not necessarily the sponsor of a clinical investigation that uses such an IVD product in a study. The manufacturer of such an IUO IVD product may legally distribute the product commercially without FDA premarket review, as long as the marketing is only for investigational use.

The marketing of unapproved and uncleared IVD products for purposes other than research or investigation (for example, for clinical diagnostic use) has led in some cases to diagnostic use of laboratory tests with unproven performance characteristics and manufacturing controls that are inadequate to ensure consistent manufacturing of the finished product. Use of such tests for clinical diagnostic purposes may mislead healthcare providers and cause serious adverse health consequences to patients who are not aware that they are being diagnosed with research or investigational products. FDA is therefore issuing this guidance to remind manufacturers of the requirements applicable to RUO and IUO IVDs.

This guidance will clarify the regulatory requirements applicable to IVD products intended for research use only or investigational use only and will provide the responses of CDRH and CBER to some frequently asked questions about how products should and should not be marketed.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized will represent the Agency's current thinking on "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions." 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1723 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 809.10 have been approved under OMB control number 0910-0485; the collections in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information regarding importer entry notice have been approved under OMB control number 0910-0046.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

Dated: May 18, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: Public Health Service, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Thrombolytic Temperature-Sensitive Liposomes

Description of Technology: The subject technology discloses a novel method for inducing targeted thrombolysis in blood vessels. In this technology, a thrombolytic agent is encapsulated within temperature-sensitive liposomes. This composition is administered into the patient's blood circulation. Certain clots and vulnerable atherosclerotic processes elicit an endogenous heat that facilitates local thrombolytic drug release. The thermosensitive liposome can also be exogenously heated to at least its phase transition temperature to induce the release the thrombolytic agent from the liposome at the thrombus for targeted

thrombolysis. The temperature for activated release can be varied, depending on the specific composition of the liposome.

Applications: Thrombolysis of blood clots formed in blood vessels, primarily in thromboembolic diseases such as myocardial infarction and stroke, venous thromboembolic diseases such as deep vein thrombosis (DVT), and pulmonary embolism (PE).

Advantages:

- Due to the protection of the thrombolytic agent within the liposome structure until the time that release is induced, this technology provides for better stability and longer half-life of the agent.

- Enhanced efficacy compared to the currently used thrombolytic treatments.

- Decreased side effects compared to the currently used thrombolytic treatments.

- Potentially decreased immunogenicity.

- Lower treatment dose may be required compared to current methods using free thrombolytic agent.

- Increases safety profile and reduces the risk of dose-related intracranial hemorrhage in treated patients.

Development Status: Proof of principle has been demonstrated in vitro.

Inventors: Bradford Wood, Matt Dreher, *et al.* (NIHCC).

Patent Status: U.S. Provisional Application No. 61/473,665 filed 08 Apr 2011 (HHS Reference No. E-090-2011/0-US-01).

Relevant Publications:

1. Collen D. Staphylokinase: A potent, uniquely fibrin-selective thrombolytic agent. *Nat Med.* 1998 Mar;4(3):279-284. [PMID: 9500599]

2. Elbayoumi TA, Torchilin VP. Liposomes for targeted delivery of antithrombotic drugs. *Expert Opin Drug Deliv.* 2008 Nov;5(11):1185-1198. [PMID: 18976130]

3. Heeremans JL, Prevost R, Bekkers ME, *et al.* Thrombolytic treatment with tissue-type plasminogen activator (t-PA) containing liposomes in rabbits: A comparison with free t-PA. *Thromb Haemost.* 1995;73(3):488-494. [PMID: 7667833]

4. Tiukinhoy-Laing SD, Huang S, Klegerman M, Holland CK, McPherson DD. Ultrasound-facilitated thrombolysis using tissue-plasminogen activator-loaded echogenic liposomes. *Thromb Res.* 2007;119(6):777-784. [PMID: 16887172]

5. Needham D, Dewhirst MW. The development and testing of a new temperature sensitive drug delivery