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

**Respondents:** 55 State Developmental Disabilities Councils.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>State Developmental Disabilities Council 5-Year State Plan</td>
<td>55</td>
<td>1</td>
<td>367</td>
<td>20,185</td>
</tr>
</tbody>
</table>

**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: oira_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]

**BILLING CODE 4184–01–P**

**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**Draft Guidance for Industry and FDA Staff:** Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions.” This draft guidance document is intended for manufacturers and distributors of research use only (RUO) and investigational use only (IUO) in vitro diagnostic (IVD) products and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/TherapeuticBiologicProducts/ApprovedTherapeuticBiologicalProducts/ucm196367.htm. The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0497; the collections of information in 21 CFR part 816 have been approved under OMB control number 0910–0498; the collections of information in 21 CFR part 819 have been approved under OMB control number 0910–0499; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0500. The collections of information in 21 CFR part 821 have been approved under OMB control number 0910–0501.

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.

[FR Doc. 2011–13390 Filed 5–31–11; 8:45 am]
BILLING CODE 4160–01–P

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, HHS.

DESCRIPTION OF INVENTIONS

Liposome at the thrombus for targeted release of thrombolytic agent

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

Patent Status: U.S. Provisional Application No. 61/473,665 filed 08 Apr 2011

Relevant Publications:


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