

for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 15, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202-395-5167 or via Internet at Nicholas.A.Fraser@omb.eop.gov and to Judith B. Herman, Federal Communications Commission, via the Internet at Judith-b.herman@fcc.gov. To submit your PRA comments by email send them to: PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418-0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-0952.

Title: Proposed Demographic Information and Notifications, Second Further Notice of Proposed Rulemaking (FNPRM), CC Docket No. 98-147 and Fifth NPRM (NPRM), CC Docket No. 96-98.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 1,200 respondents; 1,200 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirements and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in 47 U.S.C. 151-154, 201, 202, 251-254, 256 and 271 of the Communications Act of 1934, as amended.

Total Annual Burden: 4,800 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the FCC. If the applicants wish to submit information which they believe is confidential, they may request

confidential treatment of such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission is seeking an extension of this information collection in order to obtain the full three year approval from OMB. There is no change to the reporting and third party disclosure requirements.

The Commission asked whether physical collocation in remote terminals presents technical or security concerns, and if so, whether these concerns warrant modification of its collocation rules. The Commission asked whether incumbent LECs should be required to provide requesting carriers with demographic and other information regarding particular remote terminals similar to the information available regarding incumbent LEC central offices. Requesting carriers use demographic and other information obtained from incumbent LECs to determine whether they wish to collocate at particular remote terminals.

This proposed information collection in the Second Further Notice of Proposed Rulemaking, FCC 98-147, will be used by the Commission, state commissions, and competitive carriers to facilitate the deployment of advanced services and other telecommunications services in implementation of section 251(c)(6) of the Communications Act of 1934, as amended.

Federal Communications Commission.

Marlene H. Dortch,
Secretary.

[FR Doc. 2013-00554 Filed 1-11-13; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL TRADE COMMISSION

Revised Jurisdictional Thresholds of the Clayton Act

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission announces the revised thresholds for interlocking directorates required by the 1990 amendment of Section 8 of the Clayton Act. Section 8 prohibits, with certain exceptions, one person from serving as a director or officer of two competing corporations if two thresholds are met. Competitor corporations are covered by Section 8 if each one has capital, surplus, and undivided profits aggregating more than \$10,000,000, with the exception that no corporation is covered if the competitive sales of either corporation are less than \$1,000,000. Section 8(a)(5) requires the Federal Trade Commission to revise

those thresholds annually, based on the change in gross national product. The new thresholds, which take effect immediately, are \$28,883,000 for Section 8(a)(1), and \$2,888,300 for Section 8(a)(2)(A).

DATES: *Effective Date:* January 14, 2013.

FOR FURTHER INFORMATION CONTACT:

James F. Mongoven, Bureau of Competition, Office of Policy and Coordination, (202) 326-2879.

Authority: 15 U.S.C. 19(a)(5).

By direction of the Commission.

Richard C. Donohue,
Acting Secretary.

[FR Doc. 2013-00482 Filed 1-11-13; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: HHS Approval of Entities that Certify Medical Review Officers (MRO).

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

Subpart M-Medical Review Officer (MRO), Section 13.1(b), "Who may serve as an MRO?" states as follows:

"Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug testing results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall publish a list in the **Federal Register** of those entities and boards that have been approved."

HHS has completed its review of entities that train and certify MROs, in accordance with requests submitted by such entities to HHS.

(1) The HHS Secretary approves the following MRO certifying entities that offer both MRO training and certification through examination: American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709, Phone: (800) 489-1839, Fax:

(919) 490-1010, Email: cferrell@aamro.com, Web site: <http://www.aamro.com/>;

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007, Phone: (847) 631-0599, Fax: (847) 483-1282, Email: mrocc@mrocc.org, Web site: <http://www.mrocc.org/>.

(2) Additionally, the HHS Secretary lists the following entities that offer MRO training as a prerequisite for MRO certification by the above-listed approved entities:

American College of Occupational and Environmental Medicine (ACOEM), 25 Northwest Point Boulevard, Suite 700, Elk Grove Village, IL 60007-1030, Phone: (847) 818-1800, Fax: (847) 818-9266, Contact Form: <http://www.acoem.org/contactacoem.aspx>, Web site: <http://www.acoem.org/>;

American Society of Addiction Medicine (ASAM), 4601 N. Park Avenue, Upper Arcade #101, Chevy Chase, MD 20815, Phone: (301) 656-3920, Fax: (301) 656-3815, Email: email@asam.org, Web site: <http://www.asam.org/>.

DATES: HHS approval is effective January 14, 2013.

FOR FURTHER INFORMATION CONTACT: Jennifer Fan, Pharm.D., J.D., Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), 1 Choke Cherry Road, Room 7-1038, Rockville, MD 20857; Telephone: (240) 276-1759; Email: jennifer.fan@samhsa.hhs.gov.

Dated: January 4, 2013.

Kathleen Sebelius,
Secretary.

[FR Doc. 2013-00476 Filed 1-11-13; 8:45 am]

BILLING CODE 4160-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0045]

Draft Guidance for Industry on Abuse-Deterrent Opioids—Evaluation and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent

Opioids—Evaluation and Labeling.” The draft guidance describes how abuse-deterrent properties of opioid analgesic products should be studied and evaluated, and what claims regarding such properties may be suitable for inclusion in labeling. In addition to general input on this draft guidance, FDA is seeking input on the research topics outlined in the final section of the draft guidance. FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance.

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 either electronic or written comments on the draft guidance by March 15, 2013.

ADDRESSES: Submit written requests for single copies of the draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Matthew Sullivan, Center for Drug Evaluation and Research (HFD-170), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3160, Silver Spring, MD 20993, 301-796-1245, matthew.sullivan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Abuse-Deterrent Opioids—Evaluation and Labeling.” Prescription opioid analgesics are an important component of modern pain management, but abuse and misuse of these products remains a serious and growing public health problem. One important effort in reducing abuse and misuse is the development of opioid analgesics specially formulated to deter abuse. FDA considers development of abuse-deterrent opioid analgesics to be a

public health priority and is encouraging their development.

This draft guidance is intended to provide industry with a framework for evaluating and labeling abuse-deterrent opioid products. The draft guidance discusses how the potentially abuse-deterrent properties of an opioid analgesic formulated to deter abuse should be studied, specifically addressing in vitro studies, pharmacokinetic studies, human abuse potential studies, and postmarket studies. The draft guidance also describes the types of information and claims that may be suitable for inclusion in labeling.

Providing a clear framework for the evaluation and labeling of the abuse-deterrent properties of opioid analgesics intended to deter abuse should help to incentivize the development of safer, less abusable opioid analgesics, and should also facilitate the dissemination of fair and accurate information regarding such products. FDA also expects that the publication of this draft guidance will stimulate a productive discussion among FDA, industry, and other stakeholders concerning the appropriate development, evaluation, and labeling of these products. In the final section of the draft guidance, FDA also lists several areas where additional scientific research and analysis would be especially helpful.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). FDA also intends to hold a public meeting to solicit additional input from affected stakeholders on the draft guidance. The guidance, when finalized, will represent the Agency’s current thinking on evaluation and labeling of abuse-deterrent opioids. 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 either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at <http://www.regulations.gov>.