

*Estimated annual burden hours:* FR 28: 3,500 hours, FR 28s: 33 hours, FR 28i: 75 hours, Total: 3,608 hours.

*General description of report:* The Application for Employment with the Board of Governors of the Federal Reserve System (Application) collects information to determine the qualifications and availability of applicants for employment with the Board of Governors of the Federal Reserve System (Board). The FR 28 collects information on education and training, employment record, military service record, and other information since the time the applicant left high school. Included with the FR 28 are two supplemental questionnaires: (1) The Applicant's Voluntary Self-Identification Form (FR 28s), which collects information on the applicant's gender and ethnic group and (2) The Research Assistant Candidate Survey of Interests (FR 28i), which collects information from candidates applying for Research Assistant (RA) positions on their level of interest in economics and related areas. The Board receives approximately 3,500 applications per year, both solicited and unsolicited, from members of the public who would like to be considered for employment at the Board. Since the applicant is usually either hired by the Board or finds other employment within the two years that the Board retains the Application, the applicant generally files the Application once.

The Application is comprised of eight sections: Background, Education and Training, Employment Record, Military Service Record, References, General, Remarks, and Notes. The first six sections collect information on specific aspects of the applicant's qualifications. The Background section collects name, address, telephone, and citizenship information and the position for which the applicant is applying. The Education and Training section collects detailed information on the applicant's educational history and skills set. The Employment Record section collects a chronological summary of work experience. The Military Service Record section collects information on service branch, rank, duties, and discharge. The References section collects information on three references. The General section collects information on criminal records, discharge from employment, willingness to travel, and relations to or acquaintances with Board staff or officers and directors of financial institutions. The Remarks section provides the applicant an opportunity to provide further information regarding his or her qualifications. The Notes section explains what is required of the

applicant prior to an interview and what may be required of the applicant if he or she is offered a position (for example, transcripts, medical examination, or drug test).

The FR 28s is comprised of four sections: (1) Name and gender, in which the applicant is asked to check the box that corresponds to gender or check "I do not wish to disclose", (2) position for which the applicant is applying, (3) ethnicity self-identification, in which the applicant is asked to choose between Hispanic or Latino or Not Hispanic or Latino, or "I do not wish to disclose," and (4) race self-identification, in which the applicant is asked to choose one or more among American Indian or Alaskan Native, Asian, Black or African-American, Native Hawaiian or Other Pacific Islander, White, or "I do not wish to disclose." The Board uses this information to comply with federal equal employment opportunity (EEO) recordkeeping and reporting requirements, other legal requirements, and as an input to its self-analysis of hiring practices. Information collected on the FR 28s has no bearing on the determination of an applicant's job-related qualifications and completion of the self-identification form is voluntary.

The FR 28i is comprised of three sections in which research assistant candidates are asked to rate their level of interest in categories of economics and related research areas, experience with various software packages and statistical programming languages, and interest in pursuing educational opportunities after leaving the Board. The FR 28i helps to streamline the recruitment process.

*Legal authorization and confidentiality:* The Board's Legal Division has determined that the Application (including the two supplemental questionnaires) is required to obtain the benefit of Board employment. It is authorized pursuant to sections 10(4) and 11(1) of the Federal Reserve Act, which provide the Federal Reserve Board broad authority over employment of staff (12 U.S.C. 244 and 248(l)). Information provided on the Application (including the two supplemental questionnaires) will be kept confidential under exemption (b)(6) of the Freedom of Information Act (FOIA) to the extent that the disclosure of information "would constitute a clearly unwarranted invasion of personal privacy." (5 U.S.C. 552(b)(6)). For example, the release of information such as an applicant's date of birth, address, phone number, and personal information regarding any references provided would likely constitute a

clearly unwarranted invasion of personal privacy, and would be kept confidential. However, the release of information such as the educational and professional qualifications of applicants would not likely constitute a clearly unwarranted invasion of personal privacy and would not be kept confidential.

*Current actions:* On July 28, 2017, the Federal Reserve published a notice in the **Federal Register** (82 FR 35202) requesting public comment for 60 days on the extension, with revision, of the Application for Employment with the Board of Governors of the Federal Reserve System. The Board proposed minor revisions to the FR 28 form, including (1) adding fields in the employment history section for job type, shift, employee status, and desired compensation, (2) adding fields in the education and training section for issue and expiration date for certifications and professional licenses, (3) adding fields in the references section for relationship, type, and length of relationship with the reference, and (4) adding fields in the submission section to allow for withdrawal of the application and a request for the applicant to provide a reason for withdrawal. In addition, the Board proposed to revise the FR 28i by adding a section to allow an open-ended response by applicants to describe how they have demonstrated attributes that are displayed by successful research assistants in the Economics Divisions. The comment period for this notice expired on September 26, 2017. The Board did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, October 20, 2017.

**Ann E. Misback,**  
*Secretary of the Board.*

[FR Doc. 2017-23150 Filed 10-24-17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-5961]

#### **In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies, and Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications; Draft Guidances for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of two draft guidances for industry entitled “In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies” (in vitro DDI guidance) and “Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications” (clinical DDI guidance). These two draft guidances will update and replace the revised draft guidance for industry entitled “Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations” issued February 21, 2012 (2012 draft guidance). These draft guidances are intended to assist drug developers in the planning and evaluation of drug-drug interaction (DDI) potential during drug development. In particular, the in vitro DDI guidance focuses on in vitro experimental approaches for evaluating metabolizing enzyme- and transporter-based drug interaction potential and how to extrapolate in vitro data to decide on the need for clinical DDI studies. The clinical DDI guidance focuses on clinical studies that evaluate the potential for DDIs, which alter a drug’s pharmacokinetics by modulating the effects of drug metabolizing enzymes and transporters, and advises sponsors on the timing and design of the clinical studies, interpretation of the results, and options for managing DDIs in patients. Together, these two draft guidances describe a systematic, risk-based approach to the assessment of DDIs.

**DATES:** Submit either electronic or written comments on these draft guidances by January 23, 2018 to ensure that the Agency considers your comment on these two draft guidances before it begins work on the final versions of these guidances.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or

confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-5961 for “In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies, and Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications; Draft Guidances for Industry; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this

information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 documents.

#### **FOR FURTHER INFORMATION CONTACT:**

Lauren Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3188, Silver Spring, MD 20903-0002, 301-796-5008, or [OCP@fda.hhs.gov](mailto:OCP@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of two draft guidances for industry entitled “In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies” and “Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications.” The concomitant use of more than one medication in a patient is common. Unanticipated, unrecognized, or mismanaged DDIs are an important cause of morbidity and mortality associated with prescription drug use and has occasionally been the basis for withdrawal of approved drugs from the market. In some instances, understanding how to safely manage a DDI can allow approval of a drug that would otherwise have an unacceptable

level of risk. Clinically relevant DDIs between an investigational drug and other drugs should therefore: (1) Be defined during drug development as part of an adequate assessment of the drug's overall benefit/risk profile; (2) be known at the time of the drug's approval; and (3) be communicated in labeling. These two draft guidances are intended to assist drug developers in the planning and evaluation of DDI potential during drug development. In particular, the in vitro DDI guidance focuses on in vitro experimental approaches for evaluating metabolizing enzyme- and transporter-based drug interaction potential, and how to extrapolate in vitro data to decide on the need for clinical DDI studies. The appendix of the in vitro DDI guidance includes considerations in the choice of in vitro experimental systems, key issues regarding in vitro experimental conditions, and a more detailed explanation of model-based DDI prediction strategies. In vitro assessments indicate the need to conduct clinical DDI studies, sponsors should consult the related clinical DDI guidance. The clinical DDI guidance focuses on clinical studies that evaluate DDIs that alter a drug's pharmacokinetics by modulating the effects of drug metabolizing enzymes and/or transporters and advises sponsors on the timing and design of the clinical studies, interpretation of the results, and options for DDI management in patients. Together, the two draft guidances describe a systematic, risk-based approach to evaluation and communication of DDIs.

In the **Federal Register** of February 21, 2012 (77 FR 9946), FDA announced the availability of a revised draft guidance entitled "Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations." We received comments on the 2012 draft guidance and have considered these comments while updating the information in the two draft guidances. In addition, new developments in the field have been incorporated to reflect the Agency's current thinking.

The Agency decided to divide the 2012 draft guidance into two guidances with one focusing on in vitro DDI evaluation and the other focusing on clinical DDI evaluation. We are publishing the two draft guidances to collect additional public comments. These new draft guidances focus on metabolism- and transporter-based drug interactions. Other types of interactions, e.g., drug-therapeutic protein interactions and pH-dependent drug interactions, are not included. Separate

guidances will be developed to cover other types of DDIs. In addition, a draft guidance specific to Section 7 (Drug Interactions) labeling will be developed to delineate the communication of DDI information in labeling.

These two draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the Agency's current thinking on "In Vitro Metabolism- and Transporter-Mediated Drug-Drug Interaction Studies" and "Clinical Drug Interaction Studies—Study Design, Data Analysis, and Clinical Implications." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. These guidances are not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

These draft guidances refer to previously approved collections of information found in FDA regulations. 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 314.50(d) have been approved under OMB control number 0910–0001.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 19, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–D–5966]

### Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing the availability of the draft guidance entitled "Breakthrough Devices Program; Draft Guidance for Industry and Food and Drug Administration Staff." This guidance document describes policies that FDA intends to use to implement the new Breakthrough Devices Program, established by the 21st Century Cures Act (Cures Act). The Breakthrough Devices Program supersedes and combines elements from FDA's Expedited Access Pathway (EAP), which was intended to facilitate the development and expedite review of breakthrough technologies, as well as the Priority Review Program, which implemented statutory criteria for granting priority review to premarket approval applications (PMAs) and applied those criteria to other types of premarket submissions for medical devices. This draft guidance clarifies certain principles and features of the new program, the designation criteria for Breakthrough Devices, the designation request review process, the process for withdrawing from the program, as well as the recommended information device manufacturers should provide in their designation request for entrance into the program. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by December 26, 2017 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.