

administers or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

7. To assist Medicare Advantage organizations, Part D Sponsors and PACE organizations with improving the quality of required risk adjustment data obtained from the provider that furnished the item or service. CMS will be analyzing the data received and advising MA organizations, Part D Sponsors and PACE organizations of trends and data analysis results to help improve the accuracy and completeness of data received from the provider.

8. To assist appropriate Federal agencies and CMS contractors and consultants that have a need to know the information for the purpose of assisting CMS' efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, provided that the information disclosed is relevant and necessary for that assistance.

**Note:** CMS may disclose information from this system of records, without the individual record subject's consent, for any of the following purposes referenced directly in the Privacy Act: 5 U.S.C. 552a(b)(1), (3)–(8), and (12). CMS must also disclose information from this system of records, without the individual record subject's consent, for any of the following purposes referenced directly in the Privacy Act: 5 U.S.C. 552a(b)(2), and (b)(9)–(11).

#### **ADDITIONAL PROVISIONS AFFECTING ROUTINE USE DISCLOSURES:**

This system contains Protected Health Information (PHI) as defined by HHS regulation "Standards for Privacy of Individually Identifiable Health Information" (45 CFR parts 160 and 164, 65 FR 82462 (12–28–00), subparts A and E). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the "Standards for Privacy of Individually Identifiable Health Information."

In addition, our policy will be to prohibit release even of data that is not directly identifiable, except if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the

small size, use this information to deduce the identity of the beneficiary).

**Note:** Information collected or obtained under § 1860D–15 (*i.e.*, risk adjustment data used to pay Part D plan sponsors) will be used and disclosed only in accordance with the statutory limitations under § 1860D–15(f)(2).

#### **POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM STORAGE:**

Archived records will be stored on magnetic tapes. Data that is currently in use is stored in the RAPS database.

#### **RETRIEVABILITY:**

Records will be retrieved by National Provider Identifier (NPI), beneficiary provider name, or beneficiary Health Insurance Claim Number.

#### **SAFEGUARDS:**

Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational, and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems; and to prevent unauthorized access. Access to records in the RASS will be limited to CMS personnel and contractors through password security, encryption, firewalls, and secured operating system(s).

#### **RETENTION AND DISPOSAL:**

Records (*i.e.*, enrollee diagnosis data files created in RAPS, and Risk Adjustment Factor (RAF) files created in RAS) will be maintained for a period of up to 10 years after date of creation. Any such records that are needed longer, such as to resolve claims and audit exceptions or to prosecute fraud, will be retained until such matters are resolved. Enrollee claims records are currently subject to a document preservation order and will be preserved indefinitely pending further notice from the U.S. Department of Justice (DOJ).

#### **SYSTEM MANAGER AND ADDRESS:**

Director, Division of Encounter Data and Risk Adjustment Operations, Medicare Plan Payment Group, Center for Medicare, CMS, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

#### **NOTIFICATION PROCEDURE:**

Individuals (*i.e.*, the beneficiary or provider) wishing to know if this system contains records about them should write to the system manager and include

pertinent personally identifiable information (encrypted and properly transmitted) to be used for retrieval of their records (*i.e.*, NPI or Health Insurance Claim Number).

#### **RECORD ACCESS PROCEDURE:**

Individuals seeking access to records about them in this system should follow the same instructions indicated under "Notification Procedure" and reasonably specify the record content being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2)).

#### **CONTESTING RECORD PROCEDURES:**

Individuals seeking to contest the content of information about them in this system should follow the same instructions indicated under "Notification Procedure." The request should: reasonably identify the record and specify the information being contested; state the corrective action sought; and provide the reasons for the correction, with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

#### **RECORD SOURCE CATEGORIES:**

RASS processes data extracted from RAPS and RAS IT systems to calculate the risk scores used to adjust payments to Medicare Advantage organizations, Part D plan sponsors and PACE plans. RAS receives the most current data for each Medicare Part C and Part D beneficiary from the following sources: RAPS, Common Medicare Environment (CME) also known as Medicare Beneficiary Database (MBD/CME), and National Medicare Utilization Database (NMUD). RAPS receives risk adjustment data from MA organizations and other entities defined above.

#### **SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Celeste Dade-Vinson,**

*Health Insurance Specialist, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120–03–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2000–D–0103]

### **Botanical Drug Development; Draft Guidance for Industry; 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 “Botanical Drug Development.” This guidance describes FDA’s current thinking on appropriate development plans for botanical drugs to be submitted in new drug applications (NDAs) and specific recommendations on submitting investigational new drug applications (INDs) in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the over-the-counter (OTC) drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under biologics license applications (BLAs), many scientific principles described in this guidance may also apply to these products. This draft guidance revises the guidance for industry entitled “Botanical Drug Products” issued in June 2004.

**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 October 16, 2015.

**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, 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 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:** Sau L. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4144, Silver Spring, MD 20993–0002, 301–796–2905, [Sau.Lee@fda.hhs.gov](mailto:Sau.Lee@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Botanical Drug Development.” This guidance describes the Center for Drug Evaluation and Research’s current thinking on appropriate development plans for botanical drugs to be submitted in NDAs and specific recommendations on submitting INDs in support of future NDA submissions for botanical drugs. In addition, this guidance provides general information on the OTC drug monograph system for botanical drugs. Although this guidance does not intend to provide recommendations specific to botanical drugs to be marketed under BLAs, many scientific principles described in this guidance may also apply to these products.

This guidance specifically discusses several areas in which, due to the unique nature of botanical drugs, the Agency finds it appropriate to apply regulatory policies that differ from those applied to nonbotanical drugs, such as synthetic, semi-synthetic, or otherwise highly purified or chemically modified drugs, including antibiotics derived from microorganisms. Because this guidance focuses on considerations unique to botanical drugs, policies and recommendations applicable to both botanical and nonbotanical drugs are generally not covered in this document.

This guidance revises the final guidance for industry entitled “Botanical Drug Products” issued in June 2004. The general approach to botanical drug development has remained unchanged since that time; however, based on improved understanding of botanical drugs and experience acquired in the reviews of NDAs and INDs for these drugs, specific recommendations have been modified and new sections have been added to better address late-phase development and NDA submission for botanical drugs.

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 botanical drug development. 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.

**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>.

**III. The Paperwork Reduction Act of 1995**

This guidance refers 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 guidance explains the circumstances under which FDA regulations require approval of an NDA for marketing a botanical drug product and when such a product may be marketed under an OTC drug monograph. The regulations governing the preparation and submission of an NDA are in part 314 (21 CFR part 314), and the guidance does not contain any recommendations that exceed the requirements of these regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an NDA, and OMB has approved the burden under OMB control number 0910–0001. FDA anticipates that any NDAs submitted for botanical drug products would be included under the burden estimates approved by OMB for part 314.

The regulations on the procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing OTC drug monographs, are set forth in § 330.10 (21 CFR 330.10). FDA believes that any botanical drug products that may be eligible for inclusion in an OTC drug monograph under current § 330.10 have already been or presently are being considered for such inclusion.

The guidance also provides scientific and regulatory guidance to sponsors on conducting clinical investigations of botanical drugs. The regulations governing the preparation and submission of INDs are in part 312 (21 CFR part 312). The guidance does not contain any recommendations that exceed the requirements in those regulations. FDA has estimated the information collection requirements resulting from the preparation and submission of an IND under part 312, and OMB has approved the reporting and recordkeeping burden under OMB control number 0910–0014.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0012]

#### Disease Natural History Database Development—(U24)

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of Natural History Database Development. The National Organization for Rare Disorders (NORD) is developing an Internet-based data collection tool with promise to further the accumulation of natural history data for many rare diseases. The goal of this grant is to enable NORD to further develop, refine, and disseminate the database tool.

**DATES:** Important dates are as follows:

1. The application due date is September 4, 2015.
2. The anticipated start date is September 2015.
3. The opening date is July 2015.
4. The expiration date is September 5, 2015.

**ADDRESSES:** Submit electronic applications to: <http://www.grants.gov>. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** James Kaiser, Office of Translational Sciences, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-1237, [james.kaiser@fda.hhs.gov](mailto:james.kaiser@fda.hhs.gov).

Vieda Hubbard, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240-402-7588, [Vieda.Hubbard@fda.hhs.gov](mailto:Vieda.Hubbard@fda.hhs.gov).

For more information on this funding opportunity announcement (FOA) and

to obtain detailed requirements, please refer to the full FOA located at [www.grants.gov](http://www.grants.gov). Search by Funding Opportunity Number: RFA-FD-15-038.

#### SUPPLEMENTARY INFORMATION:

##### I. Funding Opportunity Description

RFA-FD-15-038  
93.103

##### A. Background

There are an estimated 7,000 rare diseases, in total affecting approximately 30 million Americans. Most of these are serious conditions with no approved therapies. Rare diseases constitute an enormous unmet medical need.

Drug development for rare diseases, as well as for common diseases, relies on an in-depth knowledge of the diseases' natural histories. Natural history is the course of the disease in the absence of a clinical intervention (that is, treatment under clinical care or study). Natural history knowledge makes possible the design of successful and efficient drug development programs. This knowledge has wide-ranging applications at every stage of drug development, for example, insight into the mechanism of disease, which can inform proof-of-concept studies; development of biomarkers that can expedite clinical studies at every stage of drug development; recognition and understanding of phenotypes of disease that may respond more (or less) to a therapy; and knowledge of the aspects of disease that matter to patients, with an impact on developing drugs that have a meaningful impact on how a patient feels, functions, or survives. The lack of natural history knowledge can result in the failure of drug programs, even for drugs with great promise. Unfortunately, the natural history of rare diseases is often poorly understood.

Impediments to the understanding of the natural history of a rare disease include the small numbers of patients and the sparse dispersal of clinical experience even among the chief clinical referral centers. The rare disease community is largely composed of small, diverse groups including patient and patient-family support, nonprofit disease groups (including umbrella groups), academic researchers, and small- to medium-sized biotechnology and pharmaceutical companies. For most rare diseases there has been no mechanism to systematically collect rare disease knowledge. In addition, it has become increasingly clear that it is vitally important to collect more knowledge from living patients over time, not simply to collect currently available information. This

“longitudinal” information about individual patients is invaluable to the design of a drug development program. The rare disease community is in need of a means of collecting and analyzing this knowledge: A natural history database tool.

##### B. Research Objectives

The development of natural history databases will directly further FDA's public health mission. We anticipate that the successful implementation of a natural history database will have profound and far-reaching effects on development of therapies for rare diseases. As a basis for solid natural history knowledge of a disease it may help to make a clinical development program for a candidate therapy appear feasible, and thus a more attractive area to pharmaceutical companies for devoting a portion of their drug discovery resources. This too will lead to greater numbers of therapies for rare diseases.

##### C. Eligibility Information

Only the following organization is eligible to apply: The National Organization for Rare Disorders. NORD is uniquely qualified to apply for this grant as the only applicant. Natural history studies is an area of unmet need and there are very few efforts towards building these studies. Those efforts that exist are very limited to specific diseases (e.g., cystic fibrosis, urea cycle disorders). These individual efforts cannot and do not support other patient groups starting their own studies. Most efforts are largely focused on patient communication and patient reports through Web-based self-reporting and are not likely to conform to sufficient scientific rigor to be able to support drug development. Although patient registries exist, these are not the same thing as natural history studies, and can often be very broad and general and cannot be customized to the depth and scope needed to support multiple natural history studies in a diverse group of rare diseases. The rigor, scope, and flexibility of NORD's platform, which comes from approximately 15 years of working with the rare disease community on these efforts, is unique and directly suited to the needs of FDA.

## II. Award Information/Funds Available

##### A. Award Amount

FDA/Center for Drug Evaluation and Research intends to fund up to \$250,000, for fiscal year 2015 in support of this grant program. It is anticipated that one award will be made, not to