| Column A—What information is requested? | Column B—Put data specific to the nominated substance |
|---|---|
| Is the ingredient listed in any of the three sections of the Orange Book? | Confirm whether the ingredient is a component of an FDA-approved product. |
| Were any monographs for the ingredient found in the USP or NF monographs? | Confirm whether the ingredient is the subject of a USP or NF monograph. |
| What is the chemical name of the substance? | Chemical name. |
| What is the common name of the substance? | Common name. |
| Does the substance have a UNII Code? | UNII code. |
| What is the chemical grade of the substance? | Provide the chemical grade. |
| What is the strength, quality, stability, and purity of the ingredient? | Provide the strength, quality, stability, and purity information. |
| How is the ingredient supplied? | Describe how the ingredient is supplied (e.g., powder, liquid). |
| Is the substance recognized in foreign pharmacopeias or registered in other countries? | List the foreign pharmacopeias or other countries in which it is registered. |
| Has information been submitted about the substance to the USP for consideration of monograph development? | Put yes, no, or unknown. If yes, state the status of the monograph, if known. |
| What dosage form(s) will be compounded using the bulk drug substance? | State the dosage form(s). |
| What strength(s) will be compounded from the nominated substance? | List the strength(s) of the drug product(s) that will be compounded from the nominated substance, or a range of strengths, if known. |
| What are the anticipated route(s) of administration of the compounded drug product(s)? | List the route(s) of administration of the compounded drug product(s). |
| Are there safety and efficacy data on compounded drugs using the nominated substance? | Provide a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature. |
| Has the bulk drug substance been used previously to compound drug product(s)? | Describe past uses of the bulk drug substance in compounding. |
| What is the proposed use for the drug product(s) to be compounded with the nominated substance? | Provide information on the proposed use of the compounded drug product. |
| What is the reason for use of a compounded drug product rather than an FDA-approved product? | Provide a rationale for the use of a compounded drug product. |
| Is there any other relevant information? | Provide any other information you would like FDA to consider in evaluating the nomination. |

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in the brackets in the heading of this document. Received nominations 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.*

Dated: June 25, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–15367 Filed 7–1–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–1524]**

## Bulk Drug Substances That May Be Used To Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Revised Request for Nominations

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

**ACTION:** Notice; revised request for nominations.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is preparing to develop a list of bulk drug substances (active ingredients) that may be used to compound drug products in accordance with section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) concerning outsourcing facilities. In response to a notice published in the **Federal Register** of December 4, 2013, interested groups and individuals previously nominated a wide variety of substances for this list. However, many of those nominations were not for bulk drug substances used in compounding as active ingredients, and none included sufficient information to justify inclusion of the nominated substances on the list. To improve the efficiency of the process for developing the list of bulk drug substances that may be used to compound drug products under section 503B of the FD&C Act, FDA is providing more detailed information on what it needs to evaluate a nomination. Because the deadline for nominations has passed, FDA is reopening the nomination process so that interested persons can submit nominations of bulk drug substances and provide adequate support to justify placing the substances on the list. Bulk drug substances that were previously nominated will not be further considered unless they are renominated and adequately supported. Substances that are not adequately supported will not be placed on the list.

**DATES:** Submit written or electronic nominations for the bulk drug substances list by September 30, 2014.

**ADDRESSES:** You may submit nominations, identified by Docket No. FDA–2013–N–1524, by any of the following methods.

### Electronic Submissions

Submit electronic nominations in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

**Written Submissions**

Submit written nominations in the following ways:

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

*Instructions:* All submissions received must include the Agency name and Docket No. FDA–2013–N–1524 for this request for nominations. All nominations received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting nominations, see the ''Request for Nominations'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or nominations received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3381.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Under the Drug Quality and Security Act (Pub. L. 113–54), which added section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b), outsourcing facilities [1] may qualify for certain exemptions from the FD&C Act if the conditions set forth in the statute are satisfied. Those conditions include that an outsourcing facility does not compound drug products using a bulk drug substance unless the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need (the 503B list), or the drug product compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) (FDA drug shortage list) at the time of compounding, distribution, and dispensing, and each of the following conditions are met: (1) If an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substance complies with the monograph; (2) the bulk drug substance is manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360); and (3) the bulk drug substance is accompanied by a valid certificate of analysis (see section 503B(a)(2) of the FD&C Act).

Section 503B refers to the definition of ''bulk drug substance'' in FDA regulations at § 207.3(a)(4) (21 CFR 207.3(a)(4)). See section 503B(a)(2) of the FD&C Act. As defined in § 207.3(a)(4), a ''bulk drug substance'' is any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

An ''active ingredient'' is any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect. See 21 CFR 210.3(b)(7).

Any component other than an active ingredient is an ''inactive ingredient.'' See 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products, which commonly include flavorings, dyes, diluents, or other excipients, need not appear on the Secretary's list of bulk drug substances to be eligible for use in compounding drug products and will not be included on the list.

In a notice dated November 27, 2013, published in the **Federal Register** of December 4, 2013 (78 FR 72838), FDA requested nominations for specific bulk drug substances for the Agency to consider for placement on the 503B list. In response to that request, 753 comments were submitted to the docket, most of which nominated substances for inclusion on the bulk drug substances list. Some comments nominated several hundred substances, and approximately 10 comments nominated thousands of substances, including en bloc nominations of substances listed in the United States Pharmacopeia (USP) or National Formulary, the British Pharmacopeia, the European Pharmacopeia, the Japanese Pharmacopeia, the Food Chemicals Codex, the Homeopathic Pharmacopeia of the United States, and the USP Dietary Supplements Compendium. Several submissions referenced a spreadsheet entitled ''OTC Active Ingredients,'' available on FDA's Web site at *http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM135688.pdf.* Those submissions nominated all of the ingredients on the spreadsheet, which numbered over 1,700 entries.[2]

However, many of the nominated substances are typically inactive ingredients or foods. Some commonly used inactive ingredients are occasionally used as the active ingredient in a drug product. See 55 FR 46914 at 46916, November 7, 1990 (noting that 21 CFR 310.545 only affects the use of the listed ingredients as active ingredients for the specific indications and that some of the ingredients listed in the rule, such as sorbitol, sugars, and eucalyptol, have valid uses as inactive ingredients). Ingredients commonly used as inactive ingredients in compounded drug products, such as flavorings, dyes, diluents, or other excipients, need not appear on the Secretary's list of bulk drug substances to be eligible for use as an inactive ingredient in compounded drug products, should not be nominated, and will not be included on the list. All nominations must demonstrate how the ingredient is used as an active ingredient in a particular compounded drug product.

Further, the nominations did not include sufficient information for the Agency to evaluate the clinical need for drug products compounded using the bulk drug substance. As stated previously, section 503B requires FDA to create a list ''identifying bulk drug substances for which there is a clinical need . . . .'' Section 503B(a)(2)(A)(i) of the FD&C Act. Although this language is ambiguous, the Agency has interpreted it to mean that a clinical need to compound with a bulk drug substance exists where there is a clinical need for a specific drug product to be compounded with the nominated bulk drug substance. The Agency believes that this interpretation is consistent with both the language and purpose of

[1] ''Outsourcing facilities'' are facilities that meet certain conditions described in section 503B of the FD&C Act, including registering with FDA as an outsourcing facility.

[2] The total number of unique ingredients on the spreadsheet available on FDA's Web site and the nominations that mirrored that document is lower than this total because the same substances were listed separately for different indications, according to how they are listed in the over-the-counter (OTC) monographs and regulations.

the statute. Therefore, to qualify for placement on the 503B list, it is necessary to identify the compounded drug product for which there is a clinical need and to demonstrate that the nominated bulk drug substance is required to compound that drug product.

The nominators of the en bloc submissions provided no justification for listing any of the specific substances on the list. To the extent information about the clinical need for the use of a bulk drug substance in compounded drug products was provided at all in individual nominations, many of the comments to the docket included a statement about the need for the use of bulk drug substances in compounding generally rather than information about the specific clinical need for drug products compounded using a particular bulk drug substance. For example, many nominations included the following standardized language as the explanation of clinical need for compounding with the bulk drug substance: ''Prescribed dosage forms and strengths not available commercially. Manufacturer backorders. Possible patient sensitivities to manufactured product dyes, fillers, preservatives and other excipients.'' Such statements do not provide sufficient information for FDA to determine that there is a clinical need to compound a particular drug product from the nominated bulk drug substance. Because the information submitted with previous nominations was insufficient, FDA is unable to determine whether those substances should be included on the list.

To improve the efficiency of the process for the development of the list of bulk drug substances that may be used to compound drug products under section 503B of the FD&C Act, and because the deadline for submitting nominations has passed, FDA is reopening the nomination process so that interested persons have the opportunity to submit nominations of bulk drug substances and provide adequate support for placing them on the list. FDA will be able to evaluate only those bulk drug substances submitted in response to this notice that are supported with adequate data and information, as described in section II.

Bulk drug substances that were previously nominated will not be further considered unless they are renominated and adequately supported. Substances that are not adequately supported will not be placed on the list. FDA expects the submissions for each bulk drug substance to provide the information described in section II. For example, nominations must include sufficient information to demonstrate that a particular ingredient meets the definition of ''bulk drug substance,'' as defined in § 207.3(a)(4). See section 503B(a)(2) of the FD&C Act. The identification of an ingredient as an ''active ingredient'' in a regulation, or on a spreadsheet such as the one listing ''OTC Active Ingredients,'' is not sufficient to demonstrate that a substance is a bulk drug substance for purposes of the 503B List. En bloc nominations of substances listed in compendia, pharmacopeia, or similar reference materials cannot be placed on the list unless the Agency receives adequate information for each bulk drug substance to justify its placement on the list. FDA will only be able to consider bulk drug substances that are supported with the information requested in section II.

In section II, FDA identifies the type of information needed to support a nomination to the 503B list.

## II. Request for Nominations

### *A. Active Ingredients*

Interested groups and individuals may nominate specific bulk substances for inclusion on the list. Nominations will only be evaluated if they are for specific active ingredients that meet the definition of a bulk drug substance in § 207.3(a)(4). Nominated substances that do not meet this definition will not be included on the list.

To fully evaluate a bulk drug substance, FDA needs the following information about both the bulk drug substance being nominated and the drug product(s) that will be compounded using such substance:

1. Confirmation That the Nominated Substance Is a Bulk Drug Substance

A statement that the nominated substance is an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4), and an explanation of why the substance is considered an active ingredient when it is used in compounded drug products, citing to specific sources that describe the active properties of the substance.

2. General Background on the Bulk Drug Substance

- Ingredient name;
- chemical name;
- common name(s); and
- identifying codes, as available, from FDA's Unique Ingredient Identifiers (UNII) used in the FDA/USP Substance Registration System, available at *http://fdasis.nlm.nih.gov/srs/*. Because substance names can vary, this code, where available, will be used by the Agency to confirm the exact substance nominated and to identify multiple nominations of the same substance so the information can be reviewed together.
- Chemical grade of the ingredient;
- description of the strength, quality, stability, and purity of the ingredient;
- information about how the ingredient is supplied (e.g., powder, liquid); and
- information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development.

### *B. Clinical Need To Compound*

For FDA to be able to meaningfully evaluate a substance, the information provided regarding the clinical need for compounding with a bulk drug substance must be specific to the particular substance nominated and drug product to be compounded. A ''boilerplate'' or general explanation of clinical need for compounding with bulk drug substances will not enable FDA to conduct an adequate review. Prescribers of the compounded drug products who may be in the best position to explain why there is a clinical need for a compounded drug product may provide data in support of a nomination. The following information about clinical need is necessary to provide adequate support for nominations to the 503B list:

- A statement describing the medical condition(s) that the drug product to be compounded with the nominated bulk drug substances is intended to treat (i.e., what patient need is met by the drug product compounded with the bulk drug substance);
- a list of FDA-approved drug products, if any, that address the same medical condition;
- if there are FDA-approved drug products that address the same medical condition, an explanation of why a compounded drug product is necessary (i.e., why the approved drug product is not suitable for a particular patient population);
- if the approved drug product is not suitable for a particular patient population, an estimate of the size of the population that would need a compounded drug product (e.g., for a drug product compounded from bulk because of patient allergies or other intolerances to excipients in FDA-approved drug products, FDA expects the supporting information to include a good faith estimate of the patient

population with the specific medical condition that suffers from the allergy or intolerance, with citations to the literature regarding the incidence of the condition or a statement that a search was conducted and no references were found); [3]

- a bibliography of safety and efficacy data for the drug compounded using the nominated substance,[4] if available, including any relevant peer-reviewed medical literature; and
- if there is an FDA-approved drug product that includes the bulk drug substance nominated, an explanation of why the drug product proposed to be compounded must be compounded from bulk rather than with the FDA-approved drug product.

General or boilerplate statements regarding the need to compound from the bulk drug substance or the benefits of compounding generally will not be considered sufficient. Note that the Agency does not consider supply issues, such as backorders, that do not rise to the level of a drug shortage listed on FDA's drug shortage Web site as evidence of a clinical need for compounding with a bulk drug substance, and section 503B of the FD&C Act already allows compounding from bulk drug substances if the compounded drug product is on the FDA drug shortage list. Similarly, considerations of cost and convenience will not be considered indicators of clinical need.

*C. Information on the Drug Product That Will Be Compounded With the Bulk Drug Substance*

- Information about the dosage form(s) into which the bulk drug substance will be compounded;
- information about the strength(s) of the compounded drug product(s);
- information about the anticipated route(s) of administration of the compounded drug product(s); and
- information about the previous use(s) of the compounded drug product(s).

*D. Nomination Process*

Because the deadline for submitting nominations has passed, FDA is reopening the nomination process so that interested persons can submit nominations of bulk drug substances and have the opportunity to provide adequate support for placing them on the list. Bulk drug substances that were previously nominated need to be renominated. Nominators are encouraged to submit as much of the information identified in this document as possible. Unless adequate supporting data is received for a bulk drug substance, FDA will be unable to consider it further for inclusion on the list.

Individuals and organizations will be able to comment on nominated substances after the nomination period has closed or petition FDA to make additional list amendments after the list is published, in accordance with 21 CFR 10.30.

For efficient consolidation and review of nominations, nominators are encouraged to submit their nominations in an editable Excel file. Specifically, nominators are encouraged to format their nominations as follows:

| Column A—What information is requested? | Column B—put data specific to the nominated substance |
|---|---|
| What is the name of the nominated ingredient? | Provide the ingredient name. |
| Is the ingredient an active ingredient that meets the definition of ''bulk drug substance'' in § 207.3(a)(4)? | Provide an explanation for why it is considered an active ingredient when it is used in specific compounded drug products, and provide citations to specific sources that describe its active properties. |
| What is the chemical name of the substance? | Chemical name. |
| What is the common name of the substance? | Common name. |
| Does the substance have a UNII Code? | UNII code. |
| What is the chemical grade of the substance? | Provide the chemical grade. |
| What is the strength, quality, stability, and purity of the ingredient? | Provide the strength, quality, stability, and purity information. |
| How is the ingredient supplied? | Describe how the ingredient is supplied (e.g., powder, liquid). |
| Is the substance recognized in foreign pharmacopeias or registered in other countries? | List the foreign pharmacopeias or other countries in which it is registered. |
| Has information been submitted about the substance to the USP for consideration of monograph development? | Put yes, no, or unknown. If yes, state the status of the monograph, if known. |
| What medical condition(s) is the drug product compounded with the bulk drug substances intended to treat? | Describe the medical condition(s) that the drug product compounded with the bulk drug substances is intended to treat. |
| Are there other drug products approved by FDA to treat the same medical condition? | List the other approved treatments. |
| If there are FDA-approved drug products that address the same medical condition, why is there a clinical need for a compounded drug product? | Provide a justification for clinical need, including an estimate of the size of the population that would need the compounded drug. |
| Are there safety and efficacy data on compounded drugs using the nominated substance? | Provide a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature. |
| If there is an FDA-approved drug product that includes the bulk drug substance nominated, is it necessary to compound a drug product from the bulk drug substance rather than from the FDA-approved drug product? | Provide an explanation of why it is necessary to compound from the bulk drug substance. |
| What dosage form(s) will be compounded using the bulk drug substance? | State the dosage form(s). |
| What strength(s) will be compounded from the nominated substance? | List the strength(s) of the drug product(s) that will be compounded from the nominated substance, or a range of strengths, if known. |
| What are the anticipated route(s) of administration of the compounded drug product(s)? | List the route(s) of administration of the compounded drug product(s). |

[3] For example, if there is a need to compound a drug product from bulk drug substances due to patient sensitivity to a preservative or other excipient in the approved drug product, the supporting data is expected to set forth the number of patients for whom the drug product is prescribed that are allergic or sensitive to that particular excipient.

[4] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support a new drug application. Note that data regarding safety and efficacy, while relevant, is not indicative of a clinical need for a particular bulk drug substance, and additional information regarding the clinical need must be provided.

| Column A—What information is requested? | Column B—put data specific to the nominated substance |
|---|---|
| Has the bulk drug substance been used previously to compound drug product(s)? | Describe previous uses of the bulk drug substance in compounding. |
| Is there any other relevant information? ..... | Provide any other information you would like FDA to consider in evaluating the nomination. |

Interested persons may submit either electronic nominations to *http://www.regulations.gov* or written nominations to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of nominations. Identify nominations with the docket number found in the brackets in the heading of this document. Received nominations 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*.

Dated: June 25, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–15373 Filed 7–1–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; 67 FR 46519, as amended June 11, 2008; 73 FR 33099, as amended September 30, 2009, 78 FR 50227, as last amended January 24, 2013, 78 FR 7436). This Order of Succession supersedes the Order of Succession for the Administrator, HRSA, published at 78 FR 7436, February 1, 2013.

This notice deletes the Bureau of Health Professions; the Bureau of Clinician Recruitment and Services; and Regional Division Directors from the order of succession, and adds the Bureau of Health Workforce and Regional Administrators to HRSA's hierarchy affecting the Order of Succession. This notice reflects the new Order of Succession for HRSA.

**Section R–30, Order of Succession**

During the absence or disability of the Administrator, or in the event of a vacancy in the office, the officials designated below shall act as Administrator in the order in which they are listed:

1. Deputy Administrator;

2. Chief Operating Officer;

3. Associate Administrator, Bureau of Primary Health Care;

4. Associate Administrator, Bureau of Health Workforce;

5. Associate Administrator, HIV/AIDS Bureau;

6. Associate Administrator, Maternal and Child Health Bureau;

7. Associate Administrator, Healthcare Systems Bureau;

8. Associate Administrator, Office of Regional Operations; and

9. HRSA Regional Administrators in the order in which they have received their permanent appointment as such.

Exceptions

(a) No official listed in this section who is serving in acting or temporary capacity shall, by virtue of so serving, act as Administrator pursuant to this section.

(b) Notwithstanding the provisions of this section, during a planned period of absence, the Administrator retains the discretion to specify a different order of succession.

**Section R–40, Delegations of Authority**

All delegations of authority and redelegations of authority made to HRSA officials that were in effect immediately prior to this action, and that are consistent with this action, shall continue in effect pending further redelegation, pending further redelegation, provided they are consistent with this action.

This document is effective upon date of signature.

Dated: June 25, 2014.

**Mary K. Wakefield,**

*Administrator.*

[FR Doc. 2014–15498 Filed 7–1–14; 8:45 am]

**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 30-Day Comment Request; Population Assessment of Tobacco and Health (PATH) Study

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 6, 2014, pages 7206–7207, and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_Submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard., Room 5185; or call non-toll-free number (301)-443–8755; or Email your request,