consider whether a bulk drug substance must be used to compound a vasopressin drug product at concentrations higher than 20 U/mL. In sum, FDA finds no basis to conclude that drug products must be compounded using a bulk drug substance rather than the approved drug product.

IV. Other Issues Raised in Nominations and Comments

The nominations for nicardipine hydrochloride and vasopressin and some comments state that there could be a benefit in the availability of drug products containing each of these bulk drug substances that do not require dilution prior to administration. We note first, with respect to nicardipine hydrochloride, that two ready-to-use nicardipine drug products are FDA-approved, and the comments do not identify patients for whom these products are medically unsuitable. More broadly, as explained above, when a bulk drug substance is a component of an approved drug, FDA asks whether there is a basis to conclude that an attribute of each approved drug product makes each one medically unsuitable to treat certain patients for their condition, an interpretation that protects patients and the integrity of the drug approval process. The nominations and comments do not show that the approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations and comments establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the approved nicardipine and vasopressin drug products.[27] Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the approved drug might be mishandled by a medical professional. That is not clinical need to compound a drug product using a bulk drug substance.

The nominations for nicardipine hydrochloride and vasopressin and some comments also include statements that these substances should be added to the 503B Bulks List because compounding from the bulk drug substance could help outsourcing facilities to address drug shortages and disruptions in supply of approved drugs intended for injection. As noted above, section 503B contains a separate provision for compounding from bulk drug substances to address a drug shortage, and we do not interpret the other price- and supply-related issues advanced by the nomination to be within the meaning of ''clinical need'' for compounding with a bulk drug substance.

V. Conclusion

For the reasons stated above, we find no clinical need for an outsourcing facility to compound using the bulk drug substances nicardipine hydrochloride and vasopressin and, therefore, we are not including nicardipine hydrochloride and vasopressin on the 503B Bulks List.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03810 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0280]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 3, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Financial Disclosure by Clinical Investigators

OMB Control Number 0910–0396—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Table 1 of this document shows information that is the basis of the estimated number of respondents in tables 2 through 4.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
Drugs:				

[27] With respect to vasopressin specifically, a comment states that vasopressin cannot be produced in ready-to-use form because the approved drug product is labeled with an in-use time of 18 hours room temperature or 24 hours refrigerated once diluted. In contrast, the commenter says that it could compound a ''pre-diluted'' drug product from bulk vasopressin with a beyond-use-date (BUD) of 60 days. We note that, in accordance with CGMP provisions, outsourcing facilities can conduct stability studies on vasopressin compounded using the approved drug product to assign a BUD based on data.

TABLE 1—ESTIMATED NUMBER OF APPLICATIONS, CLINICAL TRIALS, AND INVESTIGATORS SUBJECT TO THE REGULATION BY TYPE OF APPLICATION [1]—Continued

Application type	Total number of applications	Number of applications affected	Number of trials	Number of investigators
New drug application (NDA), new molecular entity (NME)	35	26	3 to 10	3 to 100.
NDA nonNME:				
NDA efficacy supplement	173	86	1 to 3	10 to 30.
Abbreviated new drug application (ANDA)	1,152	250	1.1	2.
ANDA supplement	6,774	383	1	2.
Biologics:				
Biologics license application (BLA)	22	19	3 to 10	3 to 100.
BLA efficacy supplement	16	14	1 to 3	10 to 30.
Medical Devices:				
Premarket approval (PMA)	48	48	1 to 3	10 to 20.
PMA supplement	23	23	1 to 3	3 to 10.
Reclassification devices	3	1	1	3 to 10.
510(k)	4,000	200	1	3 to 10.

[1] Source: Agency estimates.

In the **Federal Register** of September 27, 2018 (83 FR 48819), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, however, it was not responsive to the four collection of information topics solicited and therefore this comment will not be discussed in this document.

FDA estimates the burden of this collection of information as follows:

Reporting Burden

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

FDA estimates that almost all applicants submit a certification statement under § 54.4(a)(1) and (a)(2). Preparation of the statement using Form FDA 3454 should require no more than 1 hour per study. The number of respondents is based on the estimated number of affected applications.

When certification is not possible and disclosure is made using Form FDA 3455, the applicant must describe, under § 54.4(a)(3), the financial arrangements or interests and the steps that were taken to minimize the potential for bias in the affected study. As the applicant would be fully aware of those arrangements and the steps taken to address them, describing them will be straightforward. The Agency estimates that it will take about 5 hours to prepare this narrative. Based on our experience with this collection, FDA estimates that approximately 10 percent of the respondents with affected applications will submit disclosure statements.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)—Form FDA 3454	1,050	1	1,050	1	1,050
Disclosure—54.4(a)(3)—Form FDA 3455	105	1	105	5	525
Total					1,575

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping Burden

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records regarding clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates that an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigator's file.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Recordkeeping—54.6	1,050	1	1,050	0.25	263

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Third-Party Disclosure Burden

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that the time required for this task may range from 5 to 15 minutes; we used the mean, 10 minutes, for the average burden per disclosure. The number of respondents is the sum of the number of affected applications multiplied by the mean of the estimated number of investigators for each application type (rounded) (see table 1 of this document).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
54.4(b)—Clinical Investigators	7,894	1	7,894	0.17	1,342

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded.

Our estimated burden for the information collection reflects an overall increase of 222 hours and a corresponding increase of 893 responses/records. We attribute this adjustment to an increase in the number of affected applications and the number of investigators. No program changes were made.

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03828 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1067]

Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance describes policies that FDA intends to use in evaluating bulk drug substances nominated for use in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for inclusion on the list of bulk drug substances that can be used in compounding under section 503B.

DATES: The announcement of the guidance is published in the **Federal Register** on March 4, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–1067 for ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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