description section of the FOA, will more effectively guide applicants and panel reviewers on what ANA believes are critical components of a project's application. (*Legal authority:* Section 803(c) of NAPA, as amended.)

I. Objective Review and Results: ANA's FOA currently states ''Results of the competitive objective review are taken into consideration by ACF in the selection of projects for funding; however, objective review scores and rankings are not binding. They are one element in the decision-making process.'' ANA will clarify the scoring process in this section by stating that ANA will have the discretion to Use either the actual ''raw'' score or a normalized score in order to determine the ranking of applications after the panel review has been completed. The raw score is the average of the actual scores given by the three panelists that served as peer reviewers for the application. A normalized score is a statistical method that accounts for the variability and relative nature of individual reviewers' scoring tendencies. Normalized scores are used to counteract any possible predisposition or scoring biases of individual reviewers and panels in order to make the outcome fairer for all applications. The use of a normalized score is allowable and authorized by HHS grants administration policy.

Lillian A. Sparks,

Commissioner, Administration for Native American.

[FR Doc. 2013–04383 Filed 2–25–13; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0172]

Agency Information Collection Activities: Proposed Collection; Comment Request; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in FDA's regulations on foreign clinical studies not conducted under an investigational new drug application (IND).

DATES: Submit either electronic or written comments on the collection of information by April 29, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Foreign Clinical Studies Not Conducted Under an IND—(OMB Control Number 0910–0622)—Reinstatement

Under 312.120 (21 CFR 312.120), FDA accepts foreign clinical studies not conducted under an IND as support for an IND or application for marketing approval for a drug or biological product if the studies are conducted in accordance with good clinical practices (GCP), including review and approval by an independent ethics committee (IEC).

Under § 312.120(a), FDA accepts as support for an IND or application for marketing approval a well-designed and well-conducted foreign clinical study not conducted under an IND if the study is conducted in accordance with GCP, and we are able to validate the data from the study through an onsite inspection if necessary. GCP includes review and approval by an IEC before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject before initiating a study.

Under § 312.120(b), a sponsor of a non-IND foreign study who wants to rely on that study as support for an IND or application for marketing approval must provide the following information to FDA: (1) The investigator's qualifications; (2) a description of the research facilities; (3) a detailed summary of the protocol and results of the study and, should FDA request, case records maintained by the investigator or additional background data such as hospital or other institutional records; (4) a description of the drug substance and drug product used in the study, including a description of the components, formulation, specifications, and, if available, bioavailability of the specific drug product used in the clinical study; (5) if the study is intended to support the effectiveness of a drug product, information showing that the study is adequate and well controlled under § 314.126; (6) the name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 312.3; (7) a summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion; (8) a description of how informed consent was obtained; (9) a description of what incentives, if any,

were provided to subjects to participate in the study; (10) a description of how the sponsor(s) monitored the study and ensured that the study was carried out consistently with the study protocol; and (11) a description of how investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

Section 312.120(c) specifies how sponsors or applicants can request a waiver for any of the requirements under § 312.120(a)(1) and (b). Under § 312.120(c)(1), a waiver request must contain at least one of the following: (1) An explanation why the sponsor's or applicant's compliance with the requirement is unnecessary or cannot be achieved, (2) a description of an alternative submission or course of action that satisfies the purpose of the requirement, or (3) other information justifying a waiver. A waiver request may be submitted in an IND or in an information amendment to an IND, or in an application or in an amendment or supplement to an application submitted under 21 CFR part 314 or 601. Section 312.10 sets forth requirements for sponsors who request waivers from FDA for compliance with any of the provisions in part 312, and § 314.90 sets forth requirements for applicants who request waivers from FDA for compliance with §§ 314.50 through 314.81.

FDA has approval for the submission of these waiver requests under OMB control numbers 0910–0014 for part 312 and 0910–0001 for part 314. In addition to the reporting requirements set forth in table 1 of this document, there is also a recordkeeping provision in § 312.120(d) stating how long sponsors and applicants must retain records required by § 312.120. In addition, § 312.120(b) states that any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for Agency review upon request, and also specifies sponsor recordkeeping of IEC-related information. Under § 312.120(d), if a study is submitted in support of an application for marketing approval, records must be retained for 2 years after an Agency decision on that application; if a study is submitted in support of an IND but not an application for marketing approval, records must be retained for 2 years after the submission of the IND. The retention requirements in § 312.57(c) for records and reports required under part 312 apply to these provisions, and are approved under OMB control number 0910–0014.

We estimate that 237 companies will submit a total of approximately 1,185 non-IND foreign clinical studies in support of an IND or application for marketing approval for a drug or biological product. Hour burden estimates vary due to differences in size, complexity, and duration across studies, and we estimate that complying with § 312.120 would take sponsors between 18 and 32 hours annually for each non-IND foreign clinical trial, totaling 37,920 hours ($32 \times 1{,}185$).

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

TABLE 1—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
312.120	237	5	1,185	32	37,920

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

Dated: February 21, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04422 Filed 2–25–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0714]

Richard Stowell: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Richard Stowell for a period of 3 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Stowell was convicted, as defined in section 306(*l*)(1)(B) of the FD&C Act (21 U.S.C. 335a(*l*)(1)(B)), of three felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Stowell was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 14, 2012, Mr. Stowell had not responded. Mr. Stowell's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective February 26, 2013.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On July 27, 2011, Mr. Stowell was convicted, as defined in section 306(*l*)(1)(B) of the FD&C Act, when the U.S. District Court for the Southern District of Florida accepted his plea of guilty and entered judgment against him for the following offenses: One count of conspiracy to falsely label and misbrand seafood, in violation of 18 U.S.C. 371; one count of false labeling of seafood under the Lacey Act, in violation of 16 U.S.C. 3372(d)(2) and 3373(d)(3)(A)(ii); and one count of misbranding food, in violation of 21 U.S.C. 331(a), 343(a)(1), and 333(a)(2).

FDA's finding that debarment is appropriate is based on the felony