Based on a review of data, we received 258 nominations for membership to FDA advisory committees in fiscal year (FY) 2018; 333 nominations in FY 2019; 254 nominations in FY 2020; 289 nominations in FY 2021; and 408 nominations in FY 2022. By averaging the number of nominations received annually over the past 5 years, we estimate there are approximately 308 respondents to the information collection. We estimate it takes respondents 15 minutes to complete an initial nomination, where accompanying documentation is already available or has been prepared in advance by respondents. Multiplying 15 minutes (0.25) by the number of respondents to the information collection (308) equals 77 annual burden hours.

We have also included a burden estimate for members who currently serve on FDA advisory committees who must submit an updated CV and a completed consent form annually. Currently, there are 532 authorized positions for advisory committee members. While many positions are filled, there are generally about 15 percent of member positions vacant, which leaves an average of 452 respondents. The request for the updated CV and consent form will be made through email communications by the Designated Federal Officer of the committee. The burden to the respondent is anticipated to be the same as the burden for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 113 annual hours.

To account for burden attendant to reporting information so that FDA may determine respondents' eligibility to serve as Guest Speakers, we include only those individuals who are not Federal Government employees or who are special Government employees acting in a non-official, non-governmental capacity. Based on historical information, approximately 40 Guest Speakers present at advisory committee meetings annually. The request for the form will be made through email communications by the Designated Federal Officer of the committee. We estimate each response will require 15 minutes (0.25) for a total of 10 annual hours.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 14; subpart E—members of advisory committees activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Advisory Committee Membership Nominations	308	1	308	0.25 (15 minutes)	77
Member Submission of Updated Information	452	1	452	0.25 (15 minutes)	113
Guest Speakers—Eligibility Form/Attestation	40	1	40	0.25 (15 minutes)	10
Total			800		200

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

As a result of these changes and adjustments, the information collection reflects a decrease in membership nominations, an increase in submissions of updated information, and submission of Guest Speaker forms for an overall increase of 355 responses and 88 hours annually.

Dated: February 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02961 Filed 2–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0112]

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry; 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 a draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development.'' This guidance is intended to provide a framework for considering whether and what type of long-term neurologic, sensory, and/or developmental evaluations could be useful in supporting a determination of safety of a regulated product for use in neonates, and which domains of assessment may be most pertinent. Although short-term safety evaluations may be acceptable for adults or other populations, such short-term evaluations may not identify important adverse events in the neonatal population, as latent effects may follow early-life exposures and drug treatment during the neonatal period coincides with a time of critical growth and physiologic development. Consideration of these potential long-term neurologic, sensory, and development effects in the neonatal population early in a drug development program will help ensure a safer product.

DATES: Submit either electronic or written comments on the draft guidance by April 14, 2023 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.*
- 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–2022–D–0112 for ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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 guidance to An Massaro, Office of Pediatric Therapeutics, Office of Clinical Policy and Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 32, 5th Floor, Silver Spring, MD 20993–0002, 301–467–8507; Gerri Baer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, 240–402–2865; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993–0002, 240–402–7911; Vasum Peiris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6089. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: An Massaro, Office of Pediatric Therapeutics, Office of Clinical Policy and Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 32, 5th Floor, Silver Spring, MD 20993–0002, 301–467–8507; Gerri Baer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993–0002, 240–402–2865; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 240–402–7911; and Vasum Peiris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6089.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry.''

Treatment with drugs, biological products, or devices, medical products (referred to as ''medical products'') during the neonatal period coincides with a time of critical growth and physiologic development. Although short-term safety evaluations may be acceptable for adults or other populations, such short-term evaluations may not identify important adverse events in the neonatal population, as latent effects may follow early-life exposures. Historically, most medical products used to treat neonates and young infants were not approved for use in these populations for the relevant indications, and thus long-term impacts were infrequently systematically evaluated.

Clinical investigators and sponsors of neonatal studies should consider and assess both the potential short- and long-term effects of an investigational therapy, whether novel or developed for a different indication. Prospectively designed long-term follow-up is helpful to understand medical product safety in growing and developing neonates.

Neonates should have the same access as other populations to drugs and biologics that have been adequately evaluated for optimal dosing, efficacy, and safety. There are unique conditions that occur in term or preterm neonates that will not have analogous development programs in older populations. As products are developed for unique neonatal conditions, it may be useful for novel development programs and first-in-human studies to occur in neonates, and these development programs should demonstrate long-term neurologic, sensory, and developmental safety. This guidance will discuss general, patient-specific and product-specific considerations ranging from neurodevelopmental screening through a comprehensive neurodevelopmental evaluation. It will also address what to measure in a risk assessment, when, and for how long. 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 current thinking of FDA on ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Draft Guidance for Industry.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information for submission of investigational new drug applications, 21 CFR part 312, have been approved under 0910–0014. The collections of information for submission of new drug applications, 21 CFR part 314, have been approved under 0910–0001. The collections of information for submission of biologic license applications, 21 CFR part 601, have been approved under 0910–0338. The collections of information for submission of premarket approval applications, 21 CFR part 807, subpart E; investigational device exemptions, 21 CFR part 812; premarket notifications, 21 CFR part 814, subparts A through E; humanitarian device exemptions, 21 CFR part 814, subpart H; and De Novo classification requests, 21 CFR part 860, subpart D, have been approved under OMB control numbers 0910–0120, 0910–0078, 0910–0231, 0910–0332, and 0910–0844, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: February 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02962 Filed 2–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1104]

Determination That ARISTOSPAN (Triamcinolone Hexacetonide) Injectable Suspension, 20 Milligrams/Milliliter and 5 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 milligrams (mg)/milliliter (mL) and 5 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for triamcinolone hexacetonide injectable suspension, 20 mg/mL and 5 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Diana Pomeranz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993–0002, 240–402–4654, *Diana.Pomeranz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, is the subject of NDA 016466, held by Sandoz, Inc., and initially approved on July 29, 1969. ARISTOSPAN 20 mg/mL is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, and synovitis of osteoarthritis. ARISTOSPAN 5 mg/mL is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum; and cystic tumors of an aponeurosis or tendon (ganglia).

ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL and 5 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Medexus Pharma, Inc., submitted a citizen petition dated June 9, 2022 (Docket No. FDA–2022–P–1104), under 21 CFR 10.30, requesting that the Agency determine whether ARISTOSPAN (triamcinolone hexacetonide) injectable suspension, 20 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 5 mg/mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ARISTOSPAN (triamcinolone hexacetonide) injectable