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.'' FDA 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 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 the 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss new drug application (NDA) 208646, submitted by AllerQuest, LLC, for a skin-test kit (proposed trade name PRE–PEN Plus) that combines the approved product PRE–PEN (benzylpenicilloyl polylysine for injection) with penicillin G potassium, penicilloic acid, penilloic acid, and amoxicillin sodium, for the proposed indication to detect IgE sensitization to penicillin antigens and reliably rule out the potential for immediate life-threatening penicillin allergic reactions with a high degree of probability in patients with history of possible IgE-dependent penicillin allergy. The discussion will include study design considerations, the contribution of each of the components, and whether the submitted data provide substantial evidence of efficacy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions made to the Docket (see **ADDRESSES**) on or before March 13, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 5, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 6, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Chee (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 23, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00492 Filed 1–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4615]

Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; 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 ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' This draft guidance is intended to assist holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) with their submission of required marketing status notifications.

DATES: Submit either electronic or written comments on the draft guidance by April 1, 2019 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 concerning the collection of information proposed in the draft guidance by April 1, 2019.

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–2018–D–4615 for ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' 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 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.gpo.gov/fdsys/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.

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 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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930, *elizabeth.giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' This draft guidance is intended to assist holders of NDAs and ANDAs approved under the FD&C Act with their submission of required marketing status notifications. The FDA Reauthorization Act of 2017 (Pub. L. 115–52) (FDARA) added section 506I to the FD&C Act (21 U.S.C. 356i), which imposes additional reporting requirements on NDA and ANDA holders regarding the marketing status of approved drug products. This draft guidance identifies the required content for these marketing status notifications and the format by which these notifications should be submitted to the Agency.

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 ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (44 U.S.C. 3501–3520) (the PRA), 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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing the proposed collection of information set forth in this notice of availability that would result from the submission of these FDARA notifications.

With respect to the following collection of information, FDA invites comment 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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; Draft Guidance for Industry

Description: The draft guidance describes the FDARA requirement that NDA and ANDA holders must notify FDA of the marketing status of drug products approved under an NDA and ANDA. Applicants must provide the following information:

Notification of Withdrawal from Sale: NDA and ANDA holders must provide a written notification to FDA 180 days prior to withdrawing an approved drug from sale. Pursuant to section 506I(a) of the FD&C Act, the notification of a withdrawal from sale must include the following information:

1. The National Drug Code(s) under which the drug is listed (21 CFR part 207).
2. The established name of the drug.
3. The proprietary name of the drug, if applicable.
4. The NDA or ANDA number.
5. The strength of the drug.
6. The date on which the drug is expected to no longer be available for sale.
7. The reason for the withdrawal.

The applicant should submit the notification of a withdrawal from sale in a letter to the applicable NDA or ANDA file through the electronic submissions gateway, as described in the draft guidance. The notification should prominently identify the submission as an ''ADMINISTRATIVE CHANGE/NOT AVAILABLE FOR SALE.''

Notification of Drug Not Available For Sale: NDA and ANDA holders must provide a written notification to FDA within 180 days of the date of approval of a drug if that drug will not be available for sale within 180 days of the date of approval. Pursuant to section 506I(b) of the FD&C Act, the notification that a drug is not available for sale within 180 days of the date of approval of the drug must include the following information:

1. The established name of the drug.
2. The proprietary name of the drug, if applicable.
3. The NDA or ANDA number.
4. The strength of the drug.
5. The date on which the drug will be available for sale, if known.
6. The reason for not marketing the drug after approval.

The applicant should submit the notification that a drug will not be available for sale in a letter to the applicable NDA or ANDA file through the electronic gateway. The notification should prominently identify the submission as an ''ADMINISTRATIVE CHANGE/NOT AVAILABLE FOR SALE.'' Once marketing begins, FDA recommends that the NDA or ANDA holder notify FDA of the commenced marketing in a letter to the applicable NDA or ANDA file through the electronic gateway to ensure that appropriate changes can be made in the Agency's publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book). The notification should prominently identify the submission as an ''ADMINISTRATIVE CHANGE/NOTIFICATION OF COMMERCIAL MARKETING.''

One-Time Report on Marketing Status: NDA and ANDA holders were required to provide a written notification to FDA by February 14, 2018, stating whether the NDA and ANDA holder's drug(s) in the active section of the Orange Book are available for sale or if one or more of the NDA or ANDA holder's drugs in the active section have been withdrawn from sale or have never been available for sale. This report was required to indicate whether:

1. All of the NDA or ANDA holder's drugs in the active section of the Orange Book were available for sale or
2. One or more of the NDA or ANDA holder's drugs in the active section of the Orange Book had been withdrawn from sale or had never been available for sale.

We estimate that a total of approximately 523 applicants (''number of respondents'' in table 1) will submit annually approximately 523 *Notifications of Withdrawal from Sale* as described in the draft guidance (''total annual responses'' in table 1). We estimate that preparing and submitting each notification will take approximately 30 minutes (''hours per response'' in table 1). We base our estimates for the number of applicants and the number of notifications on information from our database of NDA and ANDA submissions. Our estimate of the time applicants would need to prepare and submit each notification is based on our familiarity with receiving these types of notifications.

We estimate that a total of approximately 30 applicants (''number of respondents'' in table 1) will submit annually approximately 30 *Notifications of Drug Not Available for Sale* as described in the draft guidance (''total annual responses'' in table 1). We estimate that preparing and submitting each notification will take approximately 30 minutes (''hours per response'' in table 1). We base our estimates for the number of applicants and the number of notifications on information from our database of NDA and ANDA submissions. Our estimate of the time applicants would need to prepare and submit each notification is based on our familiarity with receiving these types of notifications. Once marketing begins, we estimate that these applicants will notify FDA of commenced marketing by submitting *Notifications of Commercial Marketing* as described in the draft guidance. We estimate that preparing and submitting each notification that commercial marketing has commenced will take approximately 15 minutes (''hours per response'' in table 1).

A total of approximately 925 applicants (''number of respondents'' in table 2) submitted approximately 10,319 One-Time Reports on Marketing Status as described in the draft guidance (''total annual responses'' in table 2). We estimate that preparing and submitting each notification as described in the draft guidance took approximately 30 minutes (''hours per response'' in table 2). We base our estimates of the number of applicants and the number of notifications on the actual number of one-time reports on marketing status submitted prior to February 14, 2018. Our estimate of the time applicants needed to prepare and submit each notification is based on our familiarity with receiving these types of notifications.

Under the PRA, FDA has already estimated and OMB has approved under control number 0910–0001 the collection of information contained in the submission of NDA and ANDA marketing status reports (*e.g.,* notification of withdrawal from sale; notification of drug not available for sale) and related amendments, supplements, and other notifications required under subpart B and subpart C of part 314 in Title 21 of the Code of Federal Regulations (see, *e.g.,* 21 CFR 314.81(b)(2)(ii)(*a*) and (b)(3)(iv)).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Notification of Withdrawal from Sale	523	1	523	0.5 (30 minutes)	261.5
Notification of Drug Not Available for Sale, and Notification that Commercial Marketing Has Commenced	30	1	30	0.75 (45 minutes)	22.5
Total					284

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

TABLE 2—ESTIMATED ONE-TIME REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
One-Time Report on Marketing Status	925	11.16	10,319	0.5 (30 minutes)	5,159.5

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 17, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00458 Filed 1–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0176]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Neurological Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 21, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's phone number is 301–977–8900; additional information available online at: *https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html?SEO_id=GMB-HI-GAIGHHF%20.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993–0002, *Aden.Asefa@fda.hhs.gov,* 301–796–0400, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On March 21, 2019, the committee will discuss and make recommendations on clinical information related to the de novo request for the NeuroAD Therapy System by Neuronix, Ltd. The NeuroAD Therapy System is intended to provide concurrent neurostimulation and cognitive training for the treatment of mild to moderate Alzheimer's dementia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 1, 2019. Oral presentations from the public will be scheduled on March 21, 2019, between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 22, 2019.