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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*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

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

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 AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 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 16, 2019.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2019–00483 Filed 1–30–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Healthy Start Evaluation and Quality Improvement, OMB No. 0915–0338—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received no later than April 1, 2019.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Healthy Start Evaluation and Quality Improvement. OMB No. 0915–0338—Revision.

*Abstract:* The National Healthy Start Program, funded through HRSA's Maternal and Child Health Bureau (MCHB), has the goal of reducing disparities in infant mortality and adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and has expanded since then to 100 grantees across 37 states and Washington, DC. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average and high rates for other adverse perinatal outcomes. These communities are often low-income and geographically, racially, ethnically, and linguistically diverse areas. Healthy Start offers services during the perinatal period (before, during, after pregnancy) and the program works with women and infants through the first 18 months after birth. The Healthy Start program pursues four goals: (1) Improve women's health, (2) improve family health and wellness, (3) promote systems change, and (4) assure impact and effectiveness. Over the past few years, MCHB has sought to implement a uniform set of data elements for monitoring and conducting an evaluation to assess grantees' progress towards these program goals. Under the current OMB approval, the data collection instruments for this evaluation include the following: The National Healthy Start Program Survey; Community Action Network Survey; Healthy Start Site Visit Protocol; Healthy Start Participant Focus Group Protocol; and six (6) client-level screening tools: (1) Demographic Intake Form, (2) Pregnancy Status/History, (3) Preconception, (4) Prenatal, (5) Postpartum, and (6) Interconception/Parenting.

In this proposed revision, MCHB plans to retain the client-level tools as well as the National Healthy Start Program Survey, and eliminate the Community Action Network Survey, Healthy Start Site Visit Protocol and Healthy Start Participant Focus Group Protocol instruments. For the 6 client-level tools, MCHB plans to consolidate them into three (3) tools: (1) Background, (2) Prenatal, and (3) Parenting Information. The purpose of these changes is to reduce time burden on grantees, interviewers, and participants by eliminating items that are duplicated across the forms. In addition to consolidating questions across tools, many individual items have been eliminated or reworded in order to focus the evaluation more clearly on program performance measures. This will shorten the revised instruments, focus them more clearly on a single purpose, and increase consideration of participant sensitivities to certain types of questions. The reduced time burden should increase overall completion of the individual client-level forms by participants, and reduce the number of skipped items within each form.

*Need and Proposed Use of the Information:* The purpose of the revised data collection instruments will be to assess grantee and client-level progress towards meeting Healthy Start program performance measures. The data will be used to conduct ongoing performance monitoring of the program, thus meeting program needs for accountability, programmatic decision-making, and ongoing quality assurance.

*Likely Respondents:* For the General Background, Prenatal, and Parenting Information client-level forms, respondents include pregnant women and women of reproductive age who are served by the Healthy Start program. For the National Healthy Start Program Survey, respondents include project directors and staff for each of the grantees.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.