TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Microwave oven safety information and instructions—1030.10(c)(5)(i) through (iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i) through (vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i) and (ii)	3	1	3	20	60
Medical laser product instructions—1040.11(a)(2)	2	1	2	10	20
Sunlamp products instructions—1040.20	1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	1	1	1	1	1
Ultrasonic therapy products—1050.10(d)(1) through (d), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

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

Based on a review of the information collection, we have made no adjustments to our burden estimate.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10373 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This information collection supports Agency implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For efficiency of Agency operations, we are revising the information collection currently approved under OMB control number 0910–0800 pertaining to human drug compounding and section 503B of the FD&C Act (21 U.S.C. 355b) to include reference to Agency guidance regarding section 503A of the FD&C Act (21 U.S.C. 355a), and to also include information collection that we attribute to a final standard memorandum of understanding (MOU) provided for by section 503A (''final standard MOU''). Finally, we are revising the title of the information collection from ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' to ''Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources.

Agency Guidance Regarding Section 503A

We are revising the information collection to include reference to the guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance is available from our website at: *https://www.fda.gov/media/94393/download.* The guidance was issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for comment at any time. The guidance communicates FDA's intention with regard to enforcement of section 503A of the FD&C Act to regulate entities that compound drugs and notes that parts of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement and explains how the provisions will be applied pending those consultations and rulemaking. Although the guidance does not include recommended information collection, we are including the guidance as a supplemental reference for respondents.

The Final Standard MOU

We are also revising the information collection to include information collection associated with the standard MOU pursuant to the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) found in section 503A of the FD&C Act. Section 503A of the FD&C Act describes the conditions under which certain drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician are exempt from certain sections of the FD&C Act. One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) The drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such a State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded, in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B) of the FD&C Act).

Section 503A(b)(3)(B) of the FD&C Act directs FDA, in consultation with the National Association of Boards of Pharmacy (NABP), to develop a standard MOU for use by States in complying with the provision that references an MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in the State and distributed outside such State. Accordingly, we have developed the document entitled, ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [Insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration,'' available in docket number FDA–2018–N–3065, which is available at: *https://www.regulations.gov/docket?D=FDA-2018-N-3065*.

For purposes of this analysis, FDA assumes that 45 States will sign the standard MOU with FDA.

Under section III.a of the final standard MOU, the State Board of Pharmacy (BOP) or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving a complaint relating to a human drug product compounded at a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue. The notification will include the following information: (1) The name and contact information of the complainant, if available; (2) the name and address of the pharmacy that is the subject of the complaint; and (3) a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint. After the State BOP or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the State BOP or other appropriate State agency will share with FDA the results of the investigation as permitted by State law. The information will include: (1) The State BOP or other appropriate State agency's assessment of whether the complaint was substantiated, if available and (2) a description and date of any actions the State BOP or other appropriate State agency has taken to address the complaint. In addition, the State BOP or other appropriate State agency will maintain records of the complaints they receive, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State BOP or other appropriate State agency receives notice of the complaint. The State BOP or other appropriate State agency will maintain these records for at least 3 years, beginning on the date of final action on a complaint or the date of a decision that the complaint requires no action.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and will notify FDA by email at *StateMOU@fda.hhs.gov* or by submission to an information sharing network as soon as possible, but no later than 5 business days, after receiving any complaint relating to a drug product compounded by a physician and distributed outside the State involving an adverse drug experience or product quality issue. The information will include, if available: (1) The name and contact information of the complainant; (2) the name and address of the physician that is the subject of the complaint; and (3) a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

In the **Federal Register** of September 10, 2018 (83 FR 45631), we published a 60-day notice requesting public comment on the proposed collection of information. We note that in the final MOU we changed the title from ''Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration'' to ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or other appropriate State Agency] and the U.S. Food and Drug Administration.'' A number of comments were received. Most comments focused on State resource issues including whether the extent, nature, and frequency of information collection and sharing was overly burdensome and whether or not the information collection imposed an unfunded mandate on State agencies. In consideration of the comments, FDA has made the following changes to the MOU:

- We have increased the time period, from 3 days to 5 business days, to communicate information about complaints that involve serious adverse drug experiences or serious product quality issues relating to a human drug product compounded at a pharmacy and complaints that involve adverse drug experiences or product quality issues relating to a human drug product compounded by a physician;
- we have increased the amount of time after the final standard MOU is available for signature from 180 days to 365 days before FDA intends to enforce the 5 percent limit in States that have not signed the final standard MOU; and
- we have coordinated with NABP to develop an information-sharing network to help reduce the information collection and sharing burden on the State BOPs or other appropriate State agencies.

We disagree that the information collections in the MOU create unfunded mandates. Entering into the MOU is voluntary. We believe the proposed collection of information satisfies the statutory objectives of providing FDA with the information it needs through the least burdensome means available. None of the comments received

provided alternative figures to the burden estimates proffered, and we therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State BOP or other appropriate State agency notifies FDA of compounding complaints	45	3	135	0.5 (30 minutes)	67.5
State BOP or other appropriate State agency identifies pharmacies that distribute inordinate amounts of compounded human drugs interstate using surveys or inspections or data submitted to an information sharing network.	45	145	6,525	1	6,525
State BOP or other appropriate State agency notifies FDA of the distribution of inordinate amounts of compounded human drug products.	45	44	1,980	0.5 (30 minutes)	990
State BOP or other appropriate State agency notifies FDA and appropriate State regulator of physicians about physicians who distribute compounded human drug products interstate.	45	5	225	0.5 (30 minutes)	112.5
State BOP or other appropriate State agency notifies FDA of a new liaison to the MOU.	13	1	13	0.2 (12 minutes)	2.6
State BOP or other appropriate State agency notifies FDA of its intent to terminate participation in the MOU.	1	1	1	0.2 (12 minutes)	0.2
Total					7,697.8

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State BOP or other appropriate State Agency Recordkeeping for 3 Years of Compounding Complaints about Drug Products Compounded at a Pharmacy	45	2	90	1	90

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Compounding MOU between FDA and State BOP or other appropriate State Agencies	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
State BOP or other appropriate State agency notifies pharmacies that compound human drugs, and the State authority that licenses or regulates physicians that its participation in the MOU has terminated	1	1	1	1	1

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

Based on our knowledge of State regulation of compounding practices and related complaints, we estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 2) will notify FDA within 5 business days of receiving any complaint relating to a human drug product compounded by a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue or any complaint relating to a drug product compounded by a physician and distributed outside the State involving any adverse drug experience or product quality issue. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 3 complaints it receives (''No. of Responses per Respondent'' in table 1, row 2), for a total of 135 notifications of complaints sent to FDA (''Total Annual Responses'' in table 1, row 2). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 1), for a total of 67.5 hours (''Total Hours'' in table 1, row 2).

We also estimate that a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Recordkeepers'' in table 2) will prepare and maintain records for 3 years of the complaints they receive, investigations of complaints, and any State action taken or response to complaints involving drug products compounded at a pharmacy and distributed outside the State. We estimate that each State BOP or other appropriate State agency will receive annually approximately 2 complaints about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy and will prepare and maintain approximately 1 record per each complaint the State BOP or other appropriate State agency receives, for a total of 2 records per State BOP or other appropriate State agency (''No. of Records per Recordkeeper'' in table 2), and a total of 90 records annually across all States (''Total Annual Records'' in table 2). We further estimate that preparing and maintaining these records will take approximately 1 hour per record (''Average Burden per Recordkeeping (in hours)'' in table 2), for a total of 90 hours (''Total Hours'' in table 2).

Under section III.b of the final standard MOU, on an annual basis, the State BOP or other appropriate State agency will identify, using surveys, reviews of records during inspections, data submitted to an information sharing network, or other mechanisms available to the State BOP or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate by collecting information regarding the number of prescription

orders for compounded human drug products distributed interstate during any calendar year and the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (*e.g.,* picked up by a patient) at the facility in which they are compounded during that same calendar year. If a pharmacy has been identified as distributing inordinate amounts of compounded human drug products interstate, the State BOP or other appropriate State agency will also collect information regarding: (1) The total number of prescription orders for sterile compounded human drug products distributed interstate; (2) the names of States in which the pharmacy is licensed; (3) the names of States into which the pharmacy distributed compounded human drug products; and (4) whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

The State BOP or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, as described in the final standard MOU. The notification will include the name and address of the pharmacy and the information that the State BOP or other appropriate State agency collected, described in the previous paragraph.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* within 30 business days of identifying a physician that has distributed compounded human drug products interstate.

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 3) will identify pharmacies that distribute inordinate amounts of compounded human drug products interstate. We estimate that each State agency will perform surveys or inspections of 145 pharmacies or use the information sharing network to identify this information (''No. of Responses per Respondent'' in table 1, row 3). We estimate that this will take approximately 1 hour per response (''average burden per response'' in table 1, row 3), for a total of 6,525 hours (''Total Hours'' in table 1, row 3). We estimate that annually a total of 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 4) will find that a pharmacy has distributed inordinate amounts of compounded human drug products interstate and notify FDA of this finding. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 44 findings it makes (''No. of Responses per Respondent'' in table 1, row 4), for a total of 1,980 notifications (''Total Annual Responses'' in table 1, row 4). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 4), for a total of 990 hours (''Total Hours'' in table 1, row 4).

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 5) will become aware of physicians that distribute compounded human drug products interstate. We estimate that each State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA annually of approximately five physicians that distribute compounded human drug products interstate (''No. of Responses per Respondent'' in table 1, row 5), for a total of 225 notifications of physicians that distribute compounded human drug products interstate sent to FDA (''Total Annual Responses'' in table 1, row 5). We estimate that preparing and submitting this information to us as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 1), for a total of 112.5 hours (''Total Hours'' in table 1, row 5).

Under section V of the final standard MOU, a State BOP or other appropriate State agency may designate a new liaison to the MOU by notifying FDA's liaison in writing. If a State BOP or other appropriate State agency's liaison becomes unavailable to fulfill its functions under the MOU, the State BOP or other appropriate State agency will name a new liaison within 2 weeks and notify FDA.

We estimate that annually a total of approximately 13 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 5) will notify FDA of a new liaison to the MOU. We estimate that each State BOP or other appropriate State will submit to FDA annually approximately 1 notification of a new liaison (''No. of Responses per Respondent'' in table 1, row 6), for a total of 13 notifications of a new liaison (''Total Annual Responses'' in table 1, row 6). We estimate that preparing and submitting each notification as described in the MOU will take approximately 0.2 hours per response (''Average Burden per Response'' in table 1, row 6), for a total of 2.6 hours (''Total Hours'' in table 1, row 6).

Under section VI of the revised final standard MOU, a State BOP or other appropriate State agency may terminate its participation in the MOU by submitting to FDA a 60 calendar day notice of termination.

We estimate that annually a total of approximately one State BOP or other appropriate State agency (''No. of Respondents'' in table 1, row 7) will notify FDA that it intends to terminate its participation in the MOU. We estimate that this State BOP or other appropriate State agency will submit to FDA annually approximately one notification of termination (''No. of Responses per Respondent'' in table 1, row 7), for a total of one notification (''Total Annual Responses'' in table 1, row 7). We estimate that preparing and submitting the notification as described in the MOU will take approximately 0.2 hours per notification (''Average Burden per Response'' in table 1, row 7), for a total of 0.2 hours (''Total Hours'' in table 1, row 7).

We estimate that annually a total of approximately one State BOP or other appropriate State agency (''No. of Respondents'' in table 3, row 2) will notify pharmacists and the State authority that licenses or regulates physicians that its participation in the MOU has terminated. We estimate that this State BOP or other appropriate State agency will distribute approximately one notification of termination (''No. of Responses per Respondent'' in table 1, row 7), for a total of one notification (''Total Annual Responses'' in table 3, row 2).

We estimate that preparing and submitting the notification as described in the MOU will take approximately 1 hour per notification (''Average Burden per Response'' in table 3, row 2), for a total of 1 hour (''Total Hours'' in table 3, row 2).

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10336 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters: Establishment

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) Office of the Secretary announces establishment of the National Advisory Committee on Children and Disasters (NACCD). The Advisory Committee will provide advice and consultation to the HHS Secretary on pediatric medical disaster planning, preparedness, response, and recovery with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response (ASPR) shall provide management and administrative oversight to support the activities of the Advisory Committee. The Office of the Secretary is accepting application submissions from qualified individuals who wish to be considered for membership on the NACCD. Up to 13 new voting members with expertise in pediatric medical disaster planning, preparedness, response, or recovery will be selected for the Committee. Please visit the NACCD website at *www.phe.gov/naccd* for all application submission information and instructions. Application submissions will be accepted for 30 calendar days from the date this posting is published in the **Federal Register**.

Application Period: The application period is from midnight (Eastern Time) May 27th–June 27th.

FOR FURTHER INFORMATION CONTACT: Maxine Kellman, DVM, Ph.D., PMP, Alternate Designated Federal Official for National Advisory Committees, Washington, DC, Office (202) 260–0447 or email *maxine.kellman@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) of 1972, the HHS Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the National Advisory Committee on Children and Disasters (NACCD). Section 2811A of the Public Health Service Act, as amended by Pandemic and All Hazard Preparedness and Advancing Innovation Act of 2019 (42 U.S.C. 300hh–10b) requires that the Secretary for Health and Human Services (HHS) establish the National Advisory Committee on Children and Disasters (NACCD) to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response provides management and administrative oversight to support the activities of the NACCD.

Description of Duties: The NACCD: (1) Provides advice and consultation with respect to the activities addressing at-risk individuals carried out as applicable and appropriate (2) evaluates and provides input with respect to the medical and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies; (3) provides advice and consultation with respect to state emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under the National Health Security Strategy; and (4) provides advice and recommendations to the HHS Secretary with respect to children and the medical and public health grants and cooperative agreements implementing the Public Health Emergency Preparedness and Hospital Preparedness Programs and other activities, as applicable to preparedness and response activities.

Structure: The Advisory Committee consists of not more than 13 voting members, including the Chairperson. Members will be appointed by the HHS Secretary, in consultation with such other Secretaries as may be appropriate, from among the nation's preeminent scientific, public health, and medical experts in areas consistent with the purpose and functions of the NACCD. Section 2811A(d)(2) of the Public Health Services (PHS) Act States:

(2) REQUIRED NON–FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including—

(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

(B) at least 2 representatives from State, local, Tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents, including emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

(D) other members as the Secretary determines appropriate, of whom—

(i) at least one such member shall represent a children's hospital;

(ii) at least one such member shall be an individual with expertise in schools or child care settings;

(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities in the following categories: Non-federal health care professionals and representatives from state, local, territorial, or tribal agencies.

The NACCD shall also have up to 12 federal, non-voting members (*ex officio*), including the following officials or their designees:

A. The Assistant Secretary for Preparedness and Response;

B. The Director of the Biomedical Advanced Research and Development Authority;

C. The Director of the Centers for Disease Control and Prevention;

D. The Commissioner of Food and Drugs;

E. The Director of the National Institutes of Health;

F. The Assistant Secretary of the Administration for Children and Families;

G. The Administrator of the Health Resources and Services Administration;

H. The Administrator of the Federal Emergency Management Agency;

I. The Administrator of the Administration for Community Living;

J. The Secretary of Education;

K. The Assistant Secretary for Mental Health and Substance Use; and

L. The Administrator of the Environmental Protection Agency.

A voting member of the NACCD shall serve for a term of three years, except