regulations in part 820 (21 CFR part 820), which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Manufacturers are required to maintain complaint files and to review and evaluate complaints for these devices under § 820.198 (21 CFR 820.198) (approved under OMB control number 0910–0073).

Complaints required to be reported in the annual logs under the proposed special controls, such as certain complaints involving unusually high invalid rates or issues with users conducting the test, may not meet the definition of a medical device report required to be reported to FDA under 21 CFR part 803 (Medical Device Reporting; currently approved under OMB control number 0910–0437), but could potentially affect the safety and effectiveness of these devices. The submission of the complaint log would provide us with earlier notification of concerns and enable us to determine whether they have been adequately addressed. The Agency usually would not evaluate this kind of complaint information until an FDA inspection, which typically occurs less frequently than annually. We believe implementing these specific reporting measures as part of the special controls would be necessary to provide a reasonable assurance of safety and effectiveness for HIV diagnostic and supplemental tests subject to the proposed order.

Finalizing the proposed order would add classification regulations for these devices in 21 CFR part 866 (Immunology and Microbiology Devices) at 21 CFR 866.3956 for the HIV serological diagnostic and supplemental tests, and 21 CFR 866.3957 for the HIV NAT diagnostic and supplemental tests, and establish special controls necessary to provide reasonable assurance of their safety and effectiveness. As described above, the special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional 510(k) submission for one of these devices. We are requesting approval to revise the scope of the information collections included in OMB control number 0910–0437 (medical device reporting) to include the information collection associated with this special control provision.

Description of Respondents: The respondents to the information collection are manufacturers of HIV diagnostic and supplemental test devices that would be subject to the proposed order, if finalized.

In the **Federal Register** of June 25, 2021 (86 FR 33708), we published a 60-day notice requesting public comment on the new reporting provisions of the proposed order. One comment was received, however it was not responsive to the four information collection topics solicited, nor did it suggest FDA revise its burden estimate.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Proposed 21 CFR 866.3956(b)(1)(iii) and 866.3957(b)(1)(iii), Submission of log to FDA	10	1	10	3	30

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

We base our estimate of the average burden per response on our experience with other types of annual report submissions. We base our estimate of the number of affected respondents on the expected number of manufacturers that would be submitting a 510(k) for a new device or changes to an existing device that would require a 510(k).

As noted above, manufacturers of the devices subject to the proposed order must already maintain complaint files and review and evaluate complaints under § 820.198. If the proposed order is finalized as proposed, we estimate it would take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit it to FDA. Although respondents may submit the information electronically through the FDA Electronic Submission Gateway, on paper, or electronic media (*e.g.,* CD, DVD) to the Center for Biologics Evaluation and Research's Document Control Center, we assume that all manufacturers will submit their logs electronically.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03437 Filed 2–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Application Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 March 21, 2022.

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 0910–0014. 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.

Investigational New Drug Application Regulations—21 CFR part 312

OMB Control Number 0910–0014—Revision

This information collection supports implementation of provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) and of the licensing provisions of the Public Health Service Act (42 U.S.C. 201 *et seq.*) that govern investigational new drugs and investigational new drug applications (INDs). Implementing regulations are found in part 312 (21 CFR part 312), and provide for the issuance of guidance documents (see § 312.145 (21 CFR 312.145)) to assist persons in complying with the applicable requirements. The information collection applies to all clinical investigations subject to section 505 of the FD&C Act and include the following types of INDs:

- An Investigator IND is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.20 (21 CFR 312.23 or 312.20). It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and FDA's review takes place.

There are two IND categories: Commercial and research (non-commercial).

General IND requirements include submitting an initial application as well as amendments to that application; submitting reports on significant revisions of clinical investigation plans; submitting information to the clinical trials data bank (*https://clinicaltrials.gov*) established by the National Institutes of Health/National Library of Medicine, including expanded information on certain clinical trials and information on the results of these clinical trials; and reporting information on a drug's safety or effectiveness. In addition, sponsors are required to provide to FDA an annual summary of the previous year's clinical experience. The regulations also include recordkeeping requirements regarding the disposition of drugs, records regarding individual case histories, and certain other documentation verifying clinical investigators' fulfillment of responsibilities.

Form FDA 1571 entitled ''Investigational New Drug Application (IND)'' and Form FDA 1572 entitled ''Statement of Investigator,'' were developed to assist respondents with the information collection and provide for uniform reporting of required data elements. The information is required to be submitted electronically. Individuals who are interested in receiving printed forms may send an email request to the FDA Forms Manager at *formsmanager@OC.FDA.GOV.* Fees may apply. Sponsors (including sponsor-investigators) interested in filing or updating a research IND may use a new web-based interface developed for use by mobile device or desktop to help in completing Form FDA 1571. The web-based interface also allows respondents to electronically submit completed Form FDA 1571 and associated files. For more information regarding Forms FDA 1571 and 1572 visit *https://www.fda.gov/news-events/expanded-access/how-complete-form-fda-1571-and-form-fda-1572.*

Human drug, biological product, and device product submissions must be accompanied by Form FDA 3674, as discussed in the guidance document entitled ''Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions'' (updated November 2017), available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions.* The guidance document provides procedural instruction on completing and submitting required information to FDA. As communicated in the instructions, the certification must accompany the application or submission and be included at the time of submission to FDA.

Regulations in part 312, subpart B, specify content and format requirements for applications, amendments, annual reporting, and withdrawals, including content and format requirements for protocol and information amendments. The regulations also explain phases of an investigation and set forth principles of IND submissions.

Regulations in part 312, subpart C, describe administrative actions pertaining to respondents' requests for and responses to clinical holds, terminations, and inactive IND status determinations, as well as various types of meetings (for example, End-of-Phase 2 and Pre-new drug application (NDA) meetings).

Regulations in part 312, subpart D, set forth sponsor and investigator responsibilities, including general responsibilities; transfer of obligations to a contract research organization; recordkeeping and record retention controls; reporting responsibilities; and responsibility for disposition of unused supply of investigational drug. The regulations also provide for investigator controls including review of ongoing investigations; compliance with requirements regarding the protection of human subjects and institutional review board assurance; and disqualification of clinical investigators.

Regulations in part 312, subpart E, sets forth requirements applicable to drugs intended to treat life-threatening and severely debilitating illnesses. The regulations establish procedures to reflect that physicians and patients accept greater risk or side effects from products that treat life-threatening and severely debilitating illnesses than they would accept from products that treat less serious illnesses. The procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated.

Regulations in part 312, subpart F, include provisions pertaining to import and export requirements; foreign clinical studies not conducted under an IND; the disclosure of data and information in an IND; and the issuance of guidance documents. We are revising the information collection to account for burden that may be associated with recommendations found in Agency guidance documents.

- The guidance document entitled ''Oversight of Clinical Investigations'' (August 2013) communicates risk-based monitoring strategies and recommends plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof. The guidance document is intended to enhance human subject protection and the quality of clinical trial data by focusing sponsor oversight on the most important aspects of study conduct and reporting. The guidance also communicates that sponsors can use a variety of approaches to fulfill

responsibilities for monitoring clinical investigator conduct and performance in IND studies, and provides a description of strategies for monitoring activities to reflect a modern, risk-based approach. The guidance document recommends that respondents develop a written comprehensive monitoring plan and describes monitoring approaches for respondents to consider (Guidance Section IV.D.).

• The guidance document entitled ''Pharmacogenomic Data Submissions'' (March 2005) provides recommendations intended to assist sponsors submitting or holding INDs, NDAs, or biologics license applications (BLAs) with submission requirements for relevant data regarding drug safety and effectiveness (including §§ 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2, and 601.12 (21 CFR 312.22, 312.23, 312.31, 312.33, 314.50, 314.81, 601.2 and 601.12)). Because the regulations were developed before the advent of widespread animal or human genetic or gene expression testing, the regulations do not specifically address when such data must be submitted. The guidance document includes content and format recommendations regarding pharmacogenomic data submissions. Although we have not received any pharmacogenomic submissions since 2013, we assume an average of 50 hours for preparing and providing information to FDA as recommended in the guidance and estimate one submission annually.

• The guidance document entitled ''Adaptive Designs for Clinical Trials of Drugs and Biologics'' (December 2019) was developed to assist sponsors and applicants submitting INDs, NDAs, BLAs, or supplemental applications on the appropriate use of adaptive designs for clinical trials to provide evidence of the effectiveness and safety of a drug or biologic. The guidance document describes important principles for designing, conducting, and reporting the results from an adaptive clinical trial, and advises sponsors on the types of information to submit to facilitate FDA evaluation of clinical trials with adaptive designs, including Bayesian adaptive and complex trials that rely on computer simulations for their design. The guidance document also helps to fulfill FDA Commitment Goals under the Prescription Drug User Fee Act pertaining to the enhancement of regulatory decision tools.

The referenced guidance documents are available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* and were issued consistent with § 312.145 to help respondents comply with requirements in part 312. In publishing the respective notices of availability for each guidance document, we included an analysis under the PRA and invited public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Regulations in part 312, subpart G, provide for drugs for investigational use in laboratory research animals or in vitro tests.

In the **Federal Register** of November 24, 2021 (86 FR 67060), we published a 60-day notice requesting public comment on the proposed collection of information. Although we received two general comments, neither discussed the four information collection topics solicited in our 60-day notice or suggested that we revise our burden estimate.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions: §§ 312.1 through 312.10					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	454	1.528	694	24	16,656
§ 312.8; requests to charge for an investigational drug	14	1.64	23	48	1,104
§ 312.10; waiver requests	5	1	5	24	120
Subtotal Subpart A Center for Biologics Evaluation and Research (CBER)			722		17,880
Subpart B—Investigational New Drug Application (IND): §§ 312.20 through 312.38 (Including Forms FDA 1571, 1572, and 3674)					
§ 312.23(a) through (f); IND content and format	2,075	3.382	7,018	300	2,105,400
§ 312.30(a) through (e); protocol amendments	1,781	4.6692	8,316	284	2,361,744
§ 312.31(b); information amendments	169	2.48	419	100	41,900
§ 312.32(c) and (d); IND safety reports	224	10.59	2,372	32	75,904
§ 312.33(a) through (f); IND annual reports	971	2.2739	2,208	360	794,880
§ 312.38(b) and (c); notifications of withdrawal of an IND	712	3.057	2,177	28	60,956
Subtotal Subpart B CBER			22,510		5,440,784
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modification	154	1.65	254	284	72,136
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	86	1.22	105	16	1,680
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	48	1.48	71	12	852
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	157	1.80	283	160	45,280
Subtotal Subpart C CBER			713		119,948

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.53(c); investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure	1,068	5.23	5,586	80	446,880
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	4	4.25	17	48	816
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
§ 312.55(a); number of investigator brochures submitted by the sponsor to each investigator	473	2.224	1,052	48	50,496
§ 312.55(b); number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
§ 312.56(b), (c), and (d); review of ongoing investigations and associated notifications; sponsor notifications	915	2.948	2,698	80	215,840
§ 312.58; inspection of records and reports by FDA	7	1	7	8	56
§ 312.64; number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.816	10,411	24	249,864
§ 312.70; disqualification of a clinical investigator by FDA	5	1	5	40	200
Subtotal Subpart D CBER			20,980		1,021,944
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350
§ 312.120(b); number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
§ 312.120(c); number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
§ 312.130; number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.342	470	8	3,760
Subtotal Subpart F CBER			3,254		93,494
Total			48,179		6,694,050

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.52(a); sponsor records for the transfer of obligations to a contract research organization.	94	2.26	212	2	424
§ 312.57; sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interest.	335	2.70	904	100	90,400
§ 312.62(a); investigator recordkeeping of the disposition of drugs.	453	1	453	40	18,120
§ 312.62(b); investigator recordkeeping of case histories of individuals.	453	1	453	40	18,120
Subtotal Subpart D CBER			2,022		127,064

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	111	1.40	155	0.5 (30 minutes)	78
§ 312.160(c) shipper records of alternative disposition of unused drugs.	111	1.40	155	0.5 (30 minutes)	78
Subtotal Subpart G CBER			310		156
Total			2,332		127,220

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	419	1	419	24	10,056
§ 312.8; requests to charge for an investigational drug	25	1.28	32	48	1,536
§ 312.10; requests to waive a requirement in part 312	68	1.5	102	24	2,448
Subtotal Subpart A Center for Drug Evaluation and Research (CDER)			553		14,040
Subpart B—Investigational New Drug Application (IND)					
§ 312.23(a) through (f); IND content and format (including Forms FDA 1571 and 3674)	4,886	1.4662	7,164	300	2,149,200
§ 312.30(a) through (e); protocol amendments	11,847	3.2367	38,346	284.25	10,899,850
§ 312.31(b); information amendments	8,094	3.30899	26,783	100	2,678,300
§ 312.32(c) and (d); IND safety reports	892	15.848	14,137	32	452,384
§ 312.33(a) through (f); IND annual reports	3,777	2.9097	10,990	360	3,956,400
§ 312.38(b) and (c); notifications of withdrawal of an IND	1,549	1.834	2,841	28	79,548
Subtotal Subpart B CDER			100,261		20,215,682
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modifications	181	1.28	232	284	65,888
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	1	1	1	16	16
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	213	1.72	367	12	4,404
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	174	2.885	502	160	80,320
Subtotal Subpart C CDER			1,102		150,628
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	7	1.14	8	48	384
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	2	1	2	48	96
§ 312.56; review of ongoing investigations and associated notifications	4,570	5.4689	24,993	80	1,999,440
§ 312.58; inspection of records and reports by FDA	73	1	73	8	584
§ 312.70; disqualification of a clinical investigator by FDA.	5	1	5	40	200
Subtotal Subpart D CDER			25,081		2,000,704

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); written certifications and written statements submitted to FDA relating to the export of an investigational drug	8	22.375	179	75	13,425
§ 312.120(b); submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	1,964	7.352	14,440	32	462,080
§ 312.120(c); waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	68	1.5	102	24	2,448
§ 312.130; requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§ 312.145; Guidance Documents:					
Oversight of Clinical Investigations (2013)	88	1.5	132	4	528
Pharmacogenomic Data Submissions (2005)	1	1	1	50	50
Adaptive Designs for Clinical Trials of Drugs and Biologics (2019)	55	4.727	260	50	13,000
Subtotal Subpart F CDER			15,117		491,555
Total			142,114		22,872,609

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.52(a); transfer of obligations to a contract research organization.	466	3.107	1,448	300	434,400
§ 312.57; records showing the receipt, shipment, or other disposition of the investigational drug and any financial interests.	13,000	1	13,000	100	1,300,000
§ 312.62(a); records on disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); records on case histories of individuals.	2,192	6.587	14,439	40	577,560
Subtotal Subpart D CDER			41,887		2,831,960
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs.	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

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

The information collection reflects program changes and adjustments. We have revised the information collection to account for burden that may be incurred by respondents who choose to adopt or implement recommendations discussed in referenced Agency guidance documents intended to assist respondents in complying with regulatory requirements in part 312. We have also made adjustments to individual collection elements, specifically with regard to protocol amendments and emergency INDs for both human drugs and biological drugs. We attribute the increase for these elements to a corresponding increase in submissions since last OMB review and approval of the information collection and the ongoing public health emergency. Finally, we have removed burden we attribute to provisions in part 312, subpart I: Expanded Access to Investigational Drugs for Treatment Use and are revising OMB control number 0910–0814 to include burden associated with information collection applicable

to these regulatory provisions for efficiency of Agency operations. As a result of these cumulative changes and adjustments, the information collection reflects an overall decrease in both annual responses and burden hours.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03432 Filed 2–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. COMIRNATY (COVID–19 Vaccine, mRNA) was approved on August 23, 2020, and a license was issued to BioNTech Manufacturing GmbH. FDA has determined that COMIRNATY (COVID–19 Vaccine, mRNA) meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that COMIRNATY (COVID–19 Vaccine, mRNA) meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH. COMIRNATY is indicated for active immunization to prevent coronavirus disease 2019 (COVID–19) caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) in individuals 16 years of age and older.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about COMIRNATY (COVID–19 Vaccine, mRNA) go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at *https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products.*

Dated: February 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03426 Filed 2–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0410]

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Peripheral and Central Nervous System Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will take place virtually on March 30, 2022, from 10 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–0410. The docket will close on March 29, 2022. Submit either electronic or written comments on this public meeting by March 29, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 29, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 29, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before March 16, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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.*