assigned 1 hour acknowledging the requirement.

Section 1114.15 is an alternative format of submitting a PMTA that meets the requirements of § 1114.7 that would reduce the burden associated with the submission and review of an application. Our estimated number of 2 respondents is based on the number estimated for postmarket reports, which is 4 bundles (which is approximately 34 products). Not all applicants will resubmit modifications to previously authorized products, so we estimate 2 bundles (which is approximately 17 products). FDA estimates further that a supplemental PMTA will take 25 percent of the time it takes to do an original submission (including EA hours) for 428 hours per response. We estimate a total of 856 burden hours for this activity.

Under § 1114.17 an applicant may utilize the resubmission format for the same tobacco product for which FDA issued a marketing denial order or for a new tobacco product that results from changes necessary to address the deficiencies described in a marketing denial order. We are estimating that out of all bundles received in 2020, 2021, and 2022, that an average of three bundles are authorized. If we receive 24 amendments to bundles yearly, we estimate based on historical data, 58 percent fail at acceptance (down to 8 bundles remaining), 17 percent fail at filing (down to 7 bundles remaining), and 25 percent receive marketing orders (5 left). We also estimate that 50 percent of the applications that receive marketing denial orders will try to resubmit in a year. Thus, this number of respondents is three (rounded up). FDA estimates that a resubmission will take 33 percent of the time it takes to complete an original submission (including EA hours) at 565 hours per response for a total of 1,695 hours.

An applicant is required to submit a PMTA and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement. FDA does not believe we will receive many waivers, so we have assigned one respondent to acknowledge the option to submit a waiver. Consistent with our other application estimates for waivers, we believe it would take .25 hours (15 minutes) per waiver for a total of .25 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1114.45; PMTA Records	39	1	39	2	78
1100.204; Pre-existing Products Records	1	1	1	2	2
1107.3; Exemptions From Substantial Equivalence (SE) Records	1	1	1	2	2
Total					82

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

Table 2 describes the annual recordkeeping burden. FDA estimates that 39 recordkeepers will maintain records at 2 hours per record. Included in this estimate are the 15 expected new recordkeepers of NTN products. Firms are also required to establish and maintain records related to SE exemption requests and pre-existing products (§ 1100.200 states that subpart C of part 1100). We expect the burden hours to be negligible for SE exemption requests. Firms would have already established the required records when submitting the SE exemption request. Similarly, we expect the hours of to be negligible for any pre-existing tobacco products that have already submitted standalone pre-existing tobacco product submissions, because firms would have established the required records when submitting the standalone pre-existing tobacco product submissions. We believe this time is usual and customary for these firms. We estimate that it would take 2 hours per record to establish the required records for a total of 4 hours.

Relative to the emergency approval by OMB our estimated burden for the information collection reflects an overall increase of 72 hours and a corresponding increase of 117 responses/records. We attribute this adjustment to the addition of NTN product submissions.

Dated: October 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22708 Filed 10–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Neonatal Research Network.

Date: November 7–8, 2022.

Closed: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2140, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Joanna Kubler-Kielb, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Room 2140, Bethesda, MD 20892, (301) 435–6916, *kielbj@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Neonatal Research Network and Maternal-Fetal Medicine Units Network: Data Coordinating Centers.

Date: November 10, 2022.

Closed: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2127D, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Luis E. Dettin, Ph.D., MS, MA, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Rm. 2127D, Bethesda, MD 20892, (301) 219–3400, *luis_dettin@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Pediatric Scientist Development Program.

Date: November 15, 2022.

Closed: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, (202) 309–7153, *jolanta.topczewska@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Maternal-Fetal Medicine Units Network: Clinical Centers.

Date: November 17–18, 2022.

Closed: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2127D, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Luis E. Dettin, Ph.D., MS, MA, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH 6710B, Rockledge Drive, Rm. 2127D, Bethesda, MD 20892, (301) 219–3400, *luis_dettin@nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Bioprinted Tissues Constructs.

Date: November 29, 2022.

Closed: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2127B, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Chi-Tso Chiu, Ph.D., Scientific Review Officer, Scientific Review Branch (SRB), Eunice Kennedy Shriver National Institute of Child Health & Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2127B, Bethesda, MD 20817, (301) 435–7486, *chiuc@mail.nih.gov.*

Name of Committee: National Institute of Child Health and Human Development Member Conflict Special Emphasis Panel.

Date: November 30, 2022.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Rm. 2125C, Bethesda, MD 20892–7510 (Virtual Meeting).

Contact Person: Moushumi Paul, Ph.D., BA, Scientific Review Officer, Scientific Review Branch (SRB), Eunice Kennedy Shriver National Institute of Child Health & Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2125C, Bethesda, MD 20817, (301) 496–3596, *Moushumi.paul@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: October 13, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–22647 Filed 10–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Member Conflict Institutional Training T32-Awards.

Date: November 4, 2022.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Fungai Chanetsa, Ph.D., MPH, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 206–B, Bethesda, MD 20817, (301) 402–9394, *fungai.chanetsa@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 13, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–22645 Filed 10–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG2022–0349]

Certificate of Alternative Compliance for the Hayden Grace, O.N. 1326783

AGENCY: Coast Guard, DHS.

ACTION: Notification of issuance of a certificate of alternative compliance.

SUMMARY: The Coast Guard announces that the Chief of Prevention, Eighth Coast Guard District has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for the HAYDEN GRACE, O.N. 1326783. We are issuing this notice because its publication is required by statute. Due to the construction and placement of mast lights, stern light, and sidelights, HAYDEN GRACE cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel's design and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard's marine safety mission.

DATES: The Certificate of Alternative Compliance was issued on October 4, 2022.

FOR FURTHER INFORMATION CONTACT: For information or questions about this notice call or email Lieutenant Commander Jessica Flennoy, District Eight, Prevention Division, U.S. Coast Guard, telephone 504–671–2156, email *Jessica.Flennoy@uscg.mil.*