CPSC's regulations list ''special packaging standards'' for a wide range of household products, including most oral prescription drugs and many nonprescription drug products (see 16 CFR 1700 for substances requiring special packaging and the relevant packaging standards and testing procedures). It should be noted that ''child-resistant'' should not be equated with ''child-proof,'' because CRP is not designed to completely eliminate the possibility of an accidental pediatric ingestion. It can only impede access to harmful products and is recognized by public health experts as only one component of preventing these events. There are different ways to make packaging child-resistant, with the most common forms being a child-resistant closure (*e.g.,* a ''safety cap'') and certain unit-dose blister packaging (*e.g.,* puncture-resistant and peel-push blisters). FDA advocates that all drugs, irrespective of the type of packaging, be stored safely out of reach and sight of children to further the overall public health efforts to address this safety issue.

Because health care professionals and consumers may not be able to determine on visual inspection whether the packaging is child-resistant, a labeling statement may help to identify this attribute. Therefore, in this guidance, we recommend text that may be appropriate to consider when including CRP statements in labeling. All of the stakeholder comments on the draft guidance were carefully reviewed and, where appropriate, clarifying edits were made in the final guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Child-Resistant Packaging Statements in Drug Product Labeling.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information for submitting labeling in original and supplemental new drug applications (NDAs), and abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) in 21 CFR 314.50(e) and (l), 314.94(a)(8), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively. The collection of information for preparing prescription drug product labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information for Drug Facts labeling under 21 CFR 201.66 has been approved under OMB control number 0910–0340. The collection of information for Medication Guides has been approved under OMB control number 0910–0393. The collection of information for submitting chemistry, manufacturing, and controls information in original and supplemental NDAs, ANDAs, and BLAs in 21 CFR 314.50(d)(1), 314.94(a)(9), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910–0001 and 0910–0338, respectively.

III. Electronic Access

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

Dated: August 8, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17433 Filed 8–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Requests for NIH Certificates of Confidentiality

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), in the Office of the Director, the National Institutes of Health (NIH) is streamlining the electronic system for the submission and processing of requests for NIH to issue Certificates of Confidentiality (CoCs).

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Pamela Reed Kearney, Division of Human Subjects Research, OER, NIH, 6705 Rockledge Dr., Building Rockledge 1, Room 812–C, Bethesda, MD 20817, or call non-toll-free number (301) 402–2512, or email your request, including your address to: *NIH-CoC-Coordinator@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Electronic Application for NIH Certificates of Confidentiality (CoC E-application System), 0925–0689, exp., date 12/31/2019 REVISION. Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: This request system provides one electronic form to be used by all research organizations that request a Certificate of Confidentiality (CoC) from NIH. As described in the authorizing legislation (Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d)), CoCs are issued by the agencies of Department of Health and Human Services (DHHS), including NIH, to authorize researchers to protect the privacy of human research subjects by prohibiting them from releasing names and identifying characteristics of

research participants to anyone not connected with the research, except in limited circumstances specified in the statute. At NIH, the issuance of CoCs has been delegated to the NIH OER in the NIH Office of the Director. NIH received 529 requests for CoCs from April 2017 through March 2018 and expects to receive approximately the same number of requests in subsequent years. The NIH has been using an online CoC system to review requests and issue CoCs since 2015. The current CoC request form includes 15 sections of information collected from research organizations. The streamlined NIH CoC electronic system will have seven sections of structured or short text fields. The information provided will be used to determine eligibility for a CoC and to issue the CoC to the requesting organization. Eligible requesting organizations that provide legally binding affirmations that they will abide by the terms of the CoC would be issued a Certificate of Confidentiality. This system is expected to increase efficiency and reduce burden for both requestors and NIH staff who currently process these requests.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 177.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
CoC Applicants—Private	372	1	20/60	124
CoC Applicants—State/local	26	1	20/60	9
CoC Applicants—Small business	53	1	20/60	18
CoC Applicants—Federal	78	1	20/60	26
Total	529			177

Dated: August 7, 2019.

Lawrence Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–17358 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 26, 2019, 10:00 a.m. to 5:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 03, 2019, 84 FR 31878.

The meeting will be held on August 20, 2019 at 9:00 a.m. to 5:00 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17400 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 4, 2019, 8:30 a.m. to September 5, 2019, 12:00 p.m., National Institutes of Health, National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room TE406 & 408, Rockville, MD 20817 which was published in the **Federal Register** on February 11, 2019, 84 FR 3203.

This meeting notice is amended to change the meeting from a face-to-face meeting on September 4, 2019, 8:30 a.m. to September 5, 2019, 12:00 p.m. to a virtual meeting on September 4, 2019 from 1:00 p.m. to 4:30 p.m. The open session will be held from 1:00 p.m. to 3:15 p.m. and the closed session will be held from 3:30 p.m. to 4:30 p.m. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). The meeting is partially closed to the public.

Dated: August 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–17399 Filed 8–13–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning; Software Products

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (''CBP'') has issued a final determination concerning the country of origin of CIS Secure Computing, Inc.'s software products for use on mobile devices and on servers and other similar network devices. Based upon the facts presented, CBP has concluded that the software products are substantially transformed in the United States for purposes of U.S. Government procurement.

DATES: The final determination was issued on August 7, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than September 13, 2019.

FOR FURTHER INFORMATION CONTACT: James Kim, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade (202) 325–0158.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on August 7, 2019, pursuant to subpart B of Part 177, U.S. Customs and Border Protection Regulations (19 CFR part 177, subpart