Signature

Dated

Privacy Act Statement for Air Passengers From People's Republic of China Relating to the Requirement To Provide Proof of a Negative COVID–19 Test Result or Documentation of Recovery

The U.S. Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 CFR 71.20 and 71.31(b), as authorized by 42 U.S.C. 264. Providing this information is mandatory for all passengers 2 years and older boarding an aircraft into the United States from the People's Republic of China, or from *Designated Airports* if they have been in the People's Republic of China in the last 10 days.

Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases.

The Privacy Act of 1974, 5 U.S.C. 552a, governs the collection and use of this information about citizens of the United States and aliens lawfully admitted for permanent residence. The information maintained by CDC will be covered by CDC's System of Records No. 09–20–0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR parts 70 and 71. See 72 FR 70867 (Dec. 13, 2007), as amended by 76 FR 4485 (Jan. 25, 2011) and 83 FR 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the **Federal Register**, and as authorized by law. Such lawful purposes may include, but are not limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with Federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at *dgmqpolicyoffice@cdc.gov* or by mailing Policy Office, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

[FR Doc. 2023–00080 Filed 1–3–23; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0461]

Format and Content of a Risk Evaluation and Mitigation Strategy Document; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Format and Content of a REMS Document.'' This final guidance describes the format for a proposed risk evaluation and mitigation strategy (REMS) document. This format was created based on extensive stakeholder feedback. This guidance finalizes the revised draft guidance of the same title issued on October 12, 2017, and announces the availability of the technical specifications document entitled ''REMS Document Technical Conformance Guide.''

DATES: The announcement of the guidance is published in the **Federal Register** on January 5, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–D–0461 for ''Format and Content of a REMS Document.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting

of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Suzanne Robottom, Center for Drug Evaluation and Research, Food and Drug Administration,10903 New Hampshire Ave, Bldg. 22, Rm. 4475, Silver Spring, MD 20993–0002, 301–796–3554, or Stephen Ripley, 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:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Format and Content of a REMS Document.'' Section 505–1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355–1) authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks (see section 505–1(a) of the FD&C Act). A REMS is a required risk management strategy that can include one or more elements to ensure that the benefits of a drug outweigh its risks (see section 505–1(e) of the FD&C Act). The REMS document should include concise information that describes the goals and requirements of a REMS as they relate to the elements described under the FD&C Act.

In the **Federal Register** of October 12, 2017 (82 FR 47529), FDA announced the availability of a revised draft guidance for industry entitled ''Format and Content of a REMS Document.'' This draft guidance communicated changes to the format of the REMS document based on stakeholder feedback that REMS requirements are not communicated to stakeholders in a clear and consistent manner. (For more general information on REMS as well as a more comprehensive discussion of the issues summarized in this paragraph, please refer to the Background Materials *http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM362078.pdf* for the July 2013 REMS Standardization and Evaluation Public Meeting.)

This guidance finalizes the revised draft guidance entitled ''Format and Content of a REMS Document'' issued on October 12, 2017. FDA considered comments received on the revised draft guidance as the guidance was finalized. Changes from the revised draft guidance to the final guidance include: revising the REMS document to add and clarify requirements participants, including the applicants, must complete to comply with the REMS, adding a reference to a new authority to require certain packaging and safe disposal technologies for drugs that pose a serious risk of abuse or overdose, adding a new section to list the statutory elements of the REMS, adding a prompt to identify the risk addressed by the REMS, and relocating the information contained in the appendix of the guidance (*i.e.,* REMS document template) to a technical specifications document entitled ''REMS Document Technical Conformance Guide'' available on FDA's website (*https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/roles-different-participants-rems*). In addition, editorial changes were made to improve clarity and consistency between the guidance and the standardized text in the REMS document template.

The guidance, along with the new technical specifications document, can be used for drafting a REMS document for a single product and shared system REMS and includes recommendations for drafting a Bifurcated REMS document.[1]

The recommendations in this guidance and the associated technical specifications document are intended to help ensure that REMS documents are clear; understandable to stakeholders; and to the extent possible, consistent in content and format, as well as support submission of a REMS document in Structured Product Labeling format, which is required starting December 28, 2022.[2]

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 the format and content of a REMS document. 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.

II. The Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements to NDAs and ANDAs have been approved under 0910–0001. The collections of information in 21 CFR part 601 pertaining to biologics license applications (BLAs) and supplements to BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to Medication Guides for prescription drug products have been approved under OMB control number 0910–0393.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/*

[1] A Bifurcated REMS Document is used when the approval of a shared system REMS may coincide with tentative approval of an abbreviated new drug application or section 505(b)(2) application (described in section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)). For more information, refer to the guidance for industry, ''Development of a Shared System REMS'' (June 2018), available at *https://www.fda.gov/media/113869/download.*

[2] See guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling Format'' (December 2020).

guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or *https://www.regulations.gov.*

Dated: December 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–28602 Filed 1–4–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Bright Futures Periodicity Schedule as Part of the HRSA-Supported Preventive Services Guidelines for Infants, Children, and Adolescents

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

ACTION: Notice.

SUMMARY: A **Federal Register** notice published on November 2, 2022, detailed and sought public comment on recommendations under development by the Bright Futures Pediatric Implementation Program (Bright Futures Program), regarding updates to the HRSA-supported preventive services guidelines for infants, children, and adolescents in the Bright Futures Periodicity Schedule. The proposed updates are specifically related to increasing the upper age limit for Human Immunodeficiency Virus (HIV) screening. The Bright Futures Program convenes health professionals to develop draft recommendations for HRSA's consideration. Ten comments were received and considered as detailed below. On December 30, 2022, HRSA accepted as final the Bright Future Program's recommended update to the HIV screening guideline. Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported preventive services guidelines for infants, children, and adolescents. The Departments of Labor, Health and Human Services, and the Treasury have previously issued regulations, which describe how group health plans and health insurance issuers apply the coverage requirements. Please see *https://mchb.hrsa.gov/programs-impact/bright-futures* for additional information.

FOR FURTHER INFORMATION CONTACT: Bethany Miller, HRSA, Maternal and Child Health Bureau, telephone: (301) 945–5156, email: *BMiller@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Under the Patient Protection and Affordable Care Act, Public Law 111–148, the preventive care and screenings set forth in HRSA-supported guidelines are required to be covered without cost-sharing by certain group health plans and health insurance issuers. The Department adopted the Bright Futures Periodicity Schedule as a HRSA-supported guideline for infants, children, and adolescents under section 2713 of the Public Health Service Act. See 75 FR 41726, 41740 (July 19, 2010). To develop recommendations for HRSA's consideration, the Bright Futures Program convenes a panel of pediatric primary care experts to conduct rigorous reviews of current scientific evidence, solicit and consider public input, and make recommendations to HRSA regarding screenings and assessments recommended at each well-child visit from infancy through adolescence. HRSA then determines whether to support, in whole or in part, the recommended updates. The schedule of preventive care and screenings for infants, children, and adolescents is reflected in the Bright Futures Periodicity Schedule. This work is supported through the Bright Futures Program via cooperative agreement with the American Academy of Pediatrics.

The Bright Futures Program convenes a panel of pediatric primary care experts that examines the evidence to develop new (and update existing) recommendations for pediatric preventive services. The Bright Futures Program also disseminates final HRSA-supported recommendations through the annual publication of the updated Bright Futures Periodicity Schedule, with associated resources for practitioners and families.

The Bright Futures Program bases its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence. Additionally, HRSA requires that the Bright Futures Program incorporate processes to assure opportunity for public comment in the development of the updated Bright Futures Periodicity Schedule.

The Bright Futures Program proposed and HRSA has accepted recommended updates to the Bright Futures Periodicity Schedule relating to increasing the upper age limit for Screening for HIV as detailed below.

Screening for HIV

In the current Bright Futures Periodicity Schedule, the age range recommended for adolescent universal screening for HIV is between the 15-year visit and 18-year visit. The Bright Futures Program proposed and HRSA has accepted an update that would expand the recommended age range for adolescent universal screening for HIV to between the 15-year visit and 21-year visit.

In the Bright Futures Periodicity Schedule, a ''dot'' with an ''arrow'' indicates a ''range during which a service may be provided.'' The previous guideline and updated guideline on HIV screening is reflected in the chart below:

TOPIC	ADOLESCENCE										
PROCEDURES	11 Y	12 Y	13 Y	14 Y	15 Y	16 Y	17 Y	18 Y	19 Y	20 Y	21 Y
HIV (Current) [30]	★	★	★	★	←—	—	•—	—→	★	★	★
HIV (Update) [30]	★	★	★	★	•	——	——	——	——	——	——→

All such screenings (universal and risk-based) within this age range are within the scope of the guideline. The update also includes an accompanying footnote to provide updated information about more frequent screening for youth assessed as at high risk of HIV infection. The full footnote reads: ''Screen adolescents for HIV at least once between the ages of 15 and 21 making every effort to preserve confidentiality of the adolescent, as per ''Human