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*Summary Excerpts from Select *Federal Register* Notices for CHPA Weekly Voice
Week of November 7, 2022

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Drugs

- **Public Meetings**

  FDA Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee; Postponement of Meeting; Notice; postponement of meeting.

  FDA is postponing the joint meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee scheduled for November 18, 2022. Future meeting dates will be announced in the Federal Register. The joint meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee was originally announced in the Federal Register of September 13, 2022 (87 FR 56071). The meeting has been postponed to allow time for FDA to review new information. Future meeting dates will be announced in the Federal Register.

  FDA Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments; Notice of public meeting; request for comments (*for CHPA members subject to DSCSA*)

  Public Meeting: **December 7-8, 2022** (*virtual meeting*)

  e-Comments will be submitted by FDA until **11:59 pm ET at the end of February 6, 2023**. Late, untimely filed comments will not be considered.

  Registration to participate is due to FDA by December 2, 2022, and should be completed by visiting https://dscsapublicmeeting2022.eventbrite.com. Meeting information for virtual participation will be emailed by December 5, 2022, to those that registered.

  Any person interested in participating in small group discussions must register by November 28, 2022, following the instructions above, and indicate your request for breakout session participation. There will be no same-day registration for breakout sessions. FDA will organize breakout sessions based on registration and interest to help ensure varied stakeholder representation, including across the pharmaceutical distribution supply chain. FDA may limit the number of participants from each organization if interest exceeds breakout session capacity.

  Request to make oral remarks must be made by **November 28, 2022**, through the registration process. No same day registration allowed for oral remarks.

FDA (the Agency or we) is announcing the following virtual public meeting entitled "Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023" to allow supply chain stakeholders an opportunity to share their perspectives. The topics to be discussed are stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023, standards for the interoperable data exchange of product tracing information, requests for product tracing information or verification from FDA for the purpose of investigating suspect or illegitimate products or for recalls, steps taken to build capacity for package-level tracing, pharmaceutical distribution supply chain best practices, and, in general, the impact that the Drug Supply Chain Security Act (DSCSA) requirements would have on public health, including patient safety and access to prescription drugs, and on stakeholders, in terms of costs, benefits, and regulatory burden.

FDA will provide a recording of the public meeting and materials from the meeting at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsaimplementation-and-readiness-efforts-2023-12072022 after the public meeting.

USPTO Joint USPTO-FDA Collaboration Initiatives; Notice of Public Listening Session and Request for Comments; Notice of public listening session; request for comments

Public Listening Session: **January 19, 2023** (*in person in Alexandria, VA, and virtual*)

Registration is required for both in person and virtual attendance. Information regarding registration can be found at www.uspto.gov/initiatives/uspto-fda-collaboration/engagements.

Registration to speak must be completed by **5 pm on January 5, 2023**. Registration to attend only must be completed by **January 17, 2024**. In person seating is limited.

The USPTO, Department of Commerce, in collaboration with the US FDA/HHS, is announcing a public listening session on January 19, 2023, titled "Listening Session on Joint USPTO-FDA Collaboration Initiatives." The purpose of the listening session is to seek public comments on proposed initiatives for collaboration between the agencies to advance President Biden's Executive Order on "Promoting Competition in the American Economy" and to promote greater access to medicines for American families. To assist in gathering public input, the USPTO and the FDA are announcing the establishment of a docket to track feedback received through this notice and a request for comments on these collaborative efforts.

- **Regulatory Information/Comment Opportunities**

FDA Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement; Notice

Starting **April 1, 2023**, FDA will accept requests to participate in the CDRP program. See the "Participation" section of this document for eligibility criteria, instructions on how to submit a request to participate, and selection criteria and process.

FDA (or Agency) is announcing the opportunity for a limited number of applicants to participate in a Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program, to facilitate the expedited CMC development of products under an

IND application, where warranted, based upon the anticipated clinical benefit of earlier patient access to the products. FDA is implementing this pilot program to facilitate CMC readiness for selected CBER- and CDER-regulated products with accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, such as those described in FDA guidance, as applicable. This notice outlines the eligibility criteria and process for submitting a request to participate in the pilot.

FDA Advancing Premarket Safety Analytics Workshop; Request for Comments; Notice; request for comment .

Comments due to FDA by **December 5, 2022**.

FDA (the Agency or we) is requesting comments on the topics discussed at a public workshop entitled "Advancing Premarket Safety Analytics Workshop" held on September 14, 2022. The purpose of the public workshop was to present FDA's work and perspective on premarket review of safety data. Because of a lack of standardization of safety data analysis and visualization, inconsistencies have been noted in how adverse events are defined, categorized, analyzed, and presented in marketing applications. The FDA CDER's OND led the development of two documents to facilitate internal review of safety data. The first document, "FDA Medical Queries," provides a standardized approach to group preferred terms of adverse events using "Medical Dictionary for Regulatory Activities" (MedDRA) terminology. The second document, "Standard Safety Tables and Figures Integrated Guide," provides standardized methods for visualization of clinical trial safety data into tables and figures. FDA values transparency and collaboration with external stakeholders; therefore, both documents are available for public comment through the docket.

At the public workshop entitled "Advancing Premarket Safety Analytics Workshop," CDER's OND presented its work and perspective related to safety analytics. The workshop provided presentations from FDA staff on the two documents "FDA Medical Queries" and "Standard Safety Tables and Figures Integrated Guide " (meeting materials available at https://healthpolicy.duke.edu/events/advancing-premarketsafety-analytics). The workshop also included panel discussions with industry representatives on "Stakeholder Perspectives Exploring Premarket Adverse Event Grouping" and "Examining Strategies for Adverse Event Analysis." FDA documents were intended as a starting point for broader discussions on best practices and innovative approaches for advancing premarket safety signal analytics. We are also seeking comment on the topics discussed at the workshop.

- **Info Collection Notices – abbreviated info provided; see notice for details**
  FDA Agency Information Collection Activities; Proposed Collection; Comment Request; Special Protocol Assessment; Guidance for Industry; Notice (*for any relevance to R&D/switch programs*)

  e-Comments will be accepted by FDA until **11:59 pm ET at the end of January 3, 2023**. Late, untimely filed comments will not be considered.

  Subject: Special Protocol Assessment OMB Control Number 0910-0470--Extension

FDA (or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. This notice solicits comments on the information collection in the guidance for industry entitled "Special Protocol Assessment" (Revision 1).

- **Guidances (Draft/Final)**

FDA Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials; Draft Guidance for Industry; Availability; Notice of availability (*for any potential relevance to R&D programs*)

Comments due to FDA by **January 3, 2023**, to ensure consideration before work begins on the final version of the guidance.

FDA (or Agency) is announcing the availability of a draft guidance for industry entitled "Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials." The purpose of this draft guidance is to outline the most appropriate methods for measuring and recording growth and evaluating pubertal development for drugs or biological products in development for pediatric use when such an assessment is necessary to support safety. This draft guidance is intended to encourage a consistent approach to collecting interpretable and accurate growth and pubertal development data. This draft guidance does not address use of growth or pubertal development data to support primary evidence of efficacy in growth disorders and does not address evaluation of nutritional status.

Draft Guidance

FDA Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program; Draft Guidance for Industry; Availability; Notice of availability .

Comments due to FDA by **January 3, 2023**, to ensure consideration before work begins on the final version of the guidance.

FDA (or Agency) is announcing the availability of a draft guidance for industry entitled "Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program." This guidance provides stakeholders with information regarding FDA's implementation of the Over-the-Counter Monograph Drug User Fee Program authorized under the FD&C Act.

Draft Guidance

Note: Please contact Barb Kochanowski if you have any questions.

FDA Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers; Draft Guidance for Industry; Availability; Notice of availability (*for relevance to R&D/switch programs*)

Comments due to FDA by **January 3, 2023**, to ensure consideration before work begins on the final version of the guidance.

FDA (or Agency) is announcing the availability of a revised draft guidance for industry entitled "Expanded Access to Investigational Drugs for Treatment Use: Questions and

Answers." Since 2017, FDA has received many questions concerning implementation of the regulatory requirements of the expanded access program. In addition, FDA developed recommendations for fulfilling the new requirements for expanded access submissions promulgated in the 21st Century Cures Act (Cures Act) (2016) and the FDA Reauthorization Act of 2017 (FDARA). FDA is providing this guidance in a question-and-answer format, addressing the most recent frequently asked questions and sharing recommendations to fulfill the new statutory requirements. This guidance revises the guidance of the same title issued in June 2016 and updated in October 2017.

Draft Guidance

FDA S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals; International Council for Harmonisation; Guidance for Industry; Availability; Notice of availability

Guidance announced in the **November 2, 2022**, *Federal Register*.
Comments may be submitted to FDA at any time.

FDA (or Agency) is announcing the availability of a final guidance for industry entitled "S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals." The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The final guidance expands the testing scheme for assessing human carcinogenic risk of pharmaceuticals by introducing an additional approach that is not described in the original S1B Guideline. The final guidance is intended to offer an integrative approach that provides specific weight of evidence criteria that inform whether a 2-year rat study is likely to add value in completing a human carcinogenicity risk assessment. The Addendum also adds a plasma exposure ratio-based approach for setting the high dose in the rasH2-Tg mouse model, while all other aspects of the recommendations for high-dose selection in ICH guidance for industry "S1C(R2) Dose Selection for Carcinogenicity Studies of Pharmaceuticals" still apply.

Final Guidance

FDA M10 Bioanalytical Method Validation and Study Sample Analysis; International Council for Harmonisation; Guidance for Industry; Availability; Notice of availability

Guidance announced in the **November 7, 2022**, *Federal Register*.
Comments may be submitted to FDA at any time.

FDA (or Agency) is announcing the availability of a final guidance for industry entitled "M10 Bioanalytical Method Validation and Study Sample Analysis." The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. The guidance describes recommendations for method validation for bioanalytical assays for nonclinical and clinical studies that generate data to support regulatory submissions, including the procedures and processes that should be characterized for chromatographic and ligand-binding assays that are used to measure the parent and active metabolites of drugs administered in nonclinical and clinical subjects. The guidance is intended to provide industry with harmonized regulatory expectations for

bioanalytical method validation of assays used to support regulatory submissions. The guidance replaces the draft guidance "M10 Bioanalytical Method Validation" issued on June 27, 2019.

Final Guidance

Medical Devices

- **Info Collection Notice – abbreviated info provided; see notice for details**
  FDA Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program; Notice

  Comments and recommendations on the information collection due to FDA by **November 28, 2022**.

  Subject: 510(k) Third-Party Review Program OMB Control Number 0910-0375—Extension

  FDA (or we) is announcing that a proposed collection of information has been submitted to OMB for review and clearance.

  FDA Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Postmarket Surveillance of Medical Devices; Notice

  Comments and recommendations on the info collection due to FDA by **December 7, 2022**. Subject: Postmarket Surveillance of Medical Devices--21 CFR Part 822 OMB Control Number 0910-0449--Extension

  FDA is announcing that a proposed collection of information has been submitted to OMB for review and clearance.

- Regulatory Information/Comment Opportunities
  FDA Microbiology Devices; Reclassification of Human Immunodeficiency Virus Viral Load Monitoring Tests; Final amendment; final order (*for any potential relevance to R&D programs*)

  Order effective: **December 5, 2022**

  FDA (the Agency or we) is issuing a final order to reclassify human immunodeficiency virus (HIV) viral load monitoring tests, post-amendments class III devices with the product code MZF, into class II (special controls), subject to premarket notification. Through this final order, FDA is also adding a new device classification regulation along with special controls that are necessary to provide a reasonable assurance of safety and effectiveness for this device type. The final order reclassifies this device type from class III (premarket approval) to class II (special controls) and will reduce the regulatory burdens associated with these devices because manufacturers will no longer be required to submit a PMA for this device type but can instead submit a less burdensome premarket notification (510(k)) and receive clearance before marketing their device.

Dietary Supplements

- **Info Collection Notice – abbreviated info provided; see notice for details**
  FDA Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Best Practices for Convening a Generally Recognized as Safe Panel; Notice

  Comments and recommendations on the information collection due to FDA by **November 28, 2022**.

  Subject: Best Practices for Convening a Generally Recognized as Safe Panel OMB Control Number 0910-NEW

  FDA is announcing that a proposed collection of information has been submitted to OMB for review and clearance.

- **Rulemaking**
  FDA Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Supply-Chain Programs and Onsite Audits; Announcement of Effective Date; Final rule; announcement of effective date

  The effective date for the amendments to 21 CFR 117.405(a)(2), 117.435(d), and 117.475(c)(2), which published in the Federal Register of September 17, 2015 (80 FR 55908), is **October 31, 2022**. The effective date for the amendments to 21 CFR 507.105(a)(2), 507.135(d), and 507.175(c)(2), which published in the Federal Register of September 17, 2015 (80 FR 56170), is **October 31, 2022**.

  FDA (or we) is announcing the effective date for requirements related to establishing and implementing supply-chain programs, records documenting supply-chain programs, and onsite audits in two final rules, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, that appeared in the Federal Register of September 17, 2015.

Cross-category/General Information

- **Regulatory Information/Comment Opportunities**
  HHS Office of the Secretary Notice of Interest Rate on Overdue Debts (*for any potential relevance to CHPA member company business operations*) (Drugs/Medical Devices/Dietary Supplements)

  Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that HHS becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities" unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute,

contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. HHS publishes this rate in the Federal Register.

The current rate of 10 1/8%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2022. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))" and "National Research Service Award Program (42 U.S.C. 288(c)(4)(B))." This interest rate will be applied to overdue debt until HHS publishes a revision.

Office of Science & Technology Policy Request for Information; Clinical Research Infrastructure and Emergency Clinical Trials: Notice of Request for Information (RFI) on Clinical Research Infrastructure and Emergency Clinical Trials (*for any potential relevance to R&D/switch programs*) (Drugs/Medical Devices/Dietary Supplements)

Comments due to OST by 5: 00 pm ET on December 27, 2022. Comments should be sent to emergencyclinicaltrials@ostp.eop.gov and include "Emergency Clinical Trials RFI" in the subject line of the email.

In accordance with the 2022 National Biodefense Strategy for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (National Biodefense Strategy) and the American Pandemic Preparedness Plan (AP3), the White House Office of Science and Technology Policy (OSTP), in partnership with the National Security Council (NSC), is leading efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies. Efforts in this area could include the establishment of a U.S.-level governance structure and outreach to a wide range of institutions, clinical trial networks, and other potential trial sites that can participate in emergency research, both domestically and internationally. A further goal of this emergency clinical trials initiative is to support the expansion of clinical research into underserved communities, and increase diversity among both trial participants and clinical trial investigators. Building U.S. capacity to carry out emergency clinical trials will enlarge and strengthen the U.S. clinical trials infrastructure overall.

NIH Office of the Secretary, Interagency Pain Research Coordinating Committee Call for Committee Membership Nominations; Notice (*for any potential nominees within CHPA member networks*) (Drugs/Medical Devices)

Nominations due to NIH by **5:00 pm ET on November 30, 2022**. Nominations must be submitted through the webform: https://www.surveymonkey.com/r/iprcc-member-nomination-form.

The HHS (Department) has created the Interagency Pain Research Coordinating Committee and is seeking nominations for this committee. The Committee will: (a) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain; (b) identify critical gaps in basic and clinical research on the symptoms and causes of pain; (c) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort; (d) make

recommendations on how best to disseminate information on pain care; and (e) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

Membership on the committee will include six (6) non-Federal members from among scientists, physicians, and other health professionals and six (6) non-Federal members of the general public who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions. Members will serve overlapping three-year terms. It is anticipated that the committee will meet at least once a year.

USPTO Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights; Request for comments; extension of comment period (*for any potential relevance to CHPA member company business operations*) (Drugs/Medical Devices/Dietary Supplements)

The USPTO is extending the comment period for the request for comments until **February 1, 2023**.

The USPTO is extending the comment period for the notice titled "Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights" that was published in the Federal Register on October 4, 2022. The notice's comment period is extended until February 1, 2023. This will be the only extension of the comment period.

CDC Delegation of Authority Under Section 564A(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3a(e)); Notice (Drugs/Medical Devices)

This delegation was approved by the Director, CDC, and is effective **October 28, 2022**.

CDC has redelegated the authority under the Federal FD&C Act to create and issue amended emergency use instructions (EUI) to inform healthcare providers or individuals to whom an eligible product, as defined under the FD&C Act, is to be administered, concerning the product's approved, licensed, or cleared conditions of use that deviate from approved labeling, standard clinical practice, and/or standard medical modality (*e.g.*, individual prescription within the patient-clinician relationship). This notice announces the redelegation of the above-mentioned authority, without the authority to redelegate, from the Director, CDC, to the Director, National Center for Immunizations and Respiratory Diseases (NCIRD).

DoJ Antitrust Division Notice (*for any potential relevance to R&D programs*) (Drugs/Medical Devices/Dietary Supplements)

Pursuant to the National Cooperative Research and Production Act of 1993 -- ASTM International Standards Notice is hereby given that on May 23, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. ("the Act"), ASTM International ("ASTM") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing

ASTM activities originating between March 11, 2022- and May 18, 2022, designated as Work Items.

A complete listing of ASTM Work Items, along with a brief description of each, is available at http://www.astm.org. On September 15, 2004, ASTM filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act on November 10, 2004 (69 FR 65226). The last notification with the Department was filed on December 14, 2021. A notice was filed in the Federal Register on March 11, 2022 (87 FR 14043).

DoJ Antitrust Division Notice Pursuant to the National Cooperative Research and Production Act of 1993 –- ASTM International Standards (*for any potential relevance to R&D programs*) (Drugs/Medical Devices/Dietary Supplements)

Notice is hereby given that on September 22, 2022, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. ("the Act"), ASTM International ("ASTM") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing ASTM activities originating between May 18, 2022, and September 13, 2022 designated as Work Items. A complete listing of ASTM Work Items, along with a brief description of each, is available at http://www.astm.org.

On September 15, 2004, ASTM filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the Federal Register pursuant to section 6(b) of the Act on November 10, 2004 (69 FR 65226). The last notification with the Department was filed on May 23, 2022. A notice was filed in the Federal Register on March 11, 2022 (87 FR 14043).

- **Info Collection Notices – abbreviated info provided; see notice for details** (*for any potential relevance to CHPA member company business operations*) (Drugs/Medical Devices/Dietary Supplements)

  US CBP Application-Permit-Special License Unlading-Lading-Overtime Services; 30-Day Notice and request for comments; Revision of an existing collection of information

  Comments due to US CBP by **November 25, 2022**, to be assured consideration.

  Subject: Application-Permit-Special License Unlading-Lading-Overtime Services

  The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

  US CBP Country of Origin Marking Requirements for Containers or Holders; 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **November 25, 2022**, to be assured consideration.

Subject: Country of Origin Marking Requirements for Containers or Holders

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

Additional Background
Section 304 of the Tariff Act of 1930, as amended, 19 U.S.C. 1304, requires each imported article of foreign origin, or its container, to be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article or container permits, with the English name of the country of origin. The marking informs the ultimate purchaser in the United States of the country of origin of the article or its container. The marking requirements for containers or holders of imported merchandise are provided for by 19 CFR 134.22(b).

US CBP Customs and Border Protection Recordkeeping Requirements; 30-Day notice and request for comments; extension without change of an existing collection of information

Comments due to US CBP by **November 25, 2022**, to be assured consideration.

Subject: Customs and Border Protection Recordkeeping Requirements

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

US CBP Delivery Ticket; 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **November 25, 2022**, to be assured consideration.

Subject: Delivery Ticket

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

Additional Background
CBP Form 6043, Delivery Ticket, is used to document transfers of imported merchandise between parties. This form collects information such as the name and address of the consignee; the name of the importing carrier; lien information; the location of where the goods originated and where they were delivered; and information about the imported merchandise. CBP Form 6043 is completed by warehouse proprietors, carriers, Foreign Trade Zone operators and other trade entities involved in transfers of imported merchandise. This form is authorized by 19 U.S.C. 1551a and 1565, and provided for by 19 CFR 4.34, 4.37 and 19.9. It is accessible at: https://www.cbp.gov/newsroom/publications/forms.

US CBP Holders or Containers Which Enter the United States Duty Free; 30-Day Notice and request for comments: Extension of an existing collection of information

Comments due to US CBP by **November 25, 2022**, to be assured consideration.

Subject: Holders or Containers Which Enter the United States Duty Free

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

Additional Background
Section 19 CFR 10.41b eliminates the need for an importer to file entry documents by instead requiring, among other things, the marking of the containers or holders to indicate the HTSUS numbers that provide for duty-free treatment of the containers or holders.

FTC Agency Information Collection Activities; Proposed Collection; Comment Request; Extension; Notice (*for any potential relevance to OTC hearing aids/CHPA member company business operations*) (Drugs/Medical Devices)

Comments due to FTC by **December 27, 2022**.

Subject: Rule Concerning Disclosure of Written Consumer Product Warranty Terms and Conditions

The FTC (or Commission) is seeking public comment on its proposal to extend for an additional three years the current Paperwork Reduction Act (PRA) clearance for information collection requirements contained in the FTC's Consumer Product Warranty Rule (Warranty Rule or Rule). The current clearance expires on February 28, 2023.

US CBP Application to Establish a Centralized Examination Station; 30-day notice and request for comments; extension of an existing collection of information

Comments due to US CBP by **November 28, 2022**, to be assured consideration.

Subject: Application to Establish a Centralized Examination Station

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

Additional Background
A Centralized Examination Station (CES) is a privately operated facility where merchandise is made available to CBP officers for physical examination. If a port director decides that a CES is needed, he or she solicits applications to operate a CES. The information contained in the application is used to determine the suitability of the applicant's facility; the fairness of fee structure; and the knowledge of cargo handling operations and of CBP procedures and regulations. The names of all principals or corporate officers and all employees who will

come in contact with uncleared cargo are also to be provided so that CBP may perform background investigations

US CBP Declaration for Free Entry of Unaccompanied Articles (CBP Form 3299); 30-day notice and request for comments; extension of an existing collection of information.

Comments due to US CBP by **November 28, 2022**, to be assured consideration.

Subject: Declaration for Free Entry of Unaccompanied Articles

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

US CBP User Fees (CBP Form 339A, 339C and 339V); 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **November 28, 2022**, to be assured consideration.

Subject: User Fees

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

FDA Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals; Notice (Drugs/Medical Devices)

Subject: Multiple topics

FDA is publishing a list of information collections that have been approved OMB.

Topics include (*see notice for complete list*)

- Export of Medical Devices; Foreign Letters of Approval; Approval expiration date: **10/31/2025**
- Center for Devices and Radiological Health Appeals Processes; Approval expiration date: **10/31/2025**
- Review Transparency & Communication for New Molecular Entity NDAs & Original BLAs; Approval expiration date: **10/31/2025**

US CBP Administrative Rulings; 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **December 1, 2022**, to be assured consideration.

Subject: Administrative Rulings

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

US CBP Cargo Container and Road Vehicle Certification for Transport under Customs Seal; 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **December 1, 2022**, to be assured consideration.

Subject: Cargo Container and Road Vehicle Certification for Transport under Customs Seal

The US CBP will be submitting the following information collection request toOMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

US CBP Protest (CBP Form 19); 30-Day Notice and request for comments; Extension of an existing collection of information

Comments due to US CBP by **December 1, 2022**, to be assured consideration.

Subject: Protest

The US CBP will be submitting the following information collection request to OMB for review and approval. The information collection is published in the Federal Register to obtain comments from the public and affected agencies.

FDA Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications by the Food and Drug Administration's Center for Devices and Radiological Health; Notice (Drugs/Medical Devices)

e-Comments will be accepted by FDA until **11:59 pm ET at the end of January 3, 2023**. Late untimely filed comments will not be considered.

Subject: Testing Communications by FDA's Center for Devices and Radiological Health OMB Control Number 0910-0678--Extension

FDA (Agency or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. This notice solicits comments on studies regarding communications by FDA's CDRH. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

FTC Information Collection Being Submitted for Review and Approval to Office of Management and Budget; Notice and request for comments (*for any potential relevance to R&D/switch programs*) (Drugs/Medical Devices)

Comments and recommendations on the proposed information collection due to FTC by **December 5, 2022**.

Subject: Section 95.2309, Frequency Coordination/Coordinator, Wireless Medical Telemetry Service

The FCC (the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might "further reduce the information collection burden for small business concerns with fewer than 25 employees." The Commission may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

FDA Information Collection Activities; Proposed Collection; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests; Notice (Drugs/Medical Devices/Dietary Supplements)

e-Comments will be accepted by the FDA until **11:59 pm ET at the end of January 6, 2023**. Late, untimely filed comments will not be considered.

Subject: Certification of Identity; Form FDA 3975 OMB Control Number 0910-0832--Extension

FDA (Agency or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. This notice solicits comments on information collection associated with certain Freedom of Information and Privacy Act requests.

- **Rulemaking**
  FDA Color Additive Certification; Increase in Fees for Certification Services; Proposed rule (Drugs/Dietary Supplements) .

  e-Comments will be accepted by FDA until **11:59 pm ET until the end of January 3, 2023**. Late, untimely filed comments will not be considered.

  FDA (or we) is proposing to amend the color additive regulation to increase the fee for certification services. The change in fees will allow FDA to continue to maintain an adequate color certification program as required by the Federal FD&C Act. The fees are intended to recover the full costs of operation of FDA's color certification program.

  EPA Phasedown of Hydrofluorocarbons: Allowance Allocation Methodology for 2024 and Later Years; Proposed rule (*for any potential relevance to R&D/Switch programs*) (Drugs/Medical Devices)

  Comments on the NPRM due to EPA by **December 19, 2022**. Comments on the information collection provisions due to OMB by **December 5, 2022**.
  Any party requesting a public hearing must notify the contact listed below under FOR FURTHER INFORMATION CONTACT by 5 pm ET on **November 8, 2022**.

If a virtual public hearing is held, it will take place on or before **November 18, 2022,** and further information will be provided at https://www.epa.gov/climate-hfcs-reduction.

The US EPA is proposing to amend existing regulations to implement certain provisions of the American Innovation and Manufacturing Act, as enacted on December 27, 2020. This rulemaking proposes to establish the methodology for allocating hydrofluorocarbon production and consumption allowances for the calendar years of 2024 through 2028. EPA is also proposing to amend the consumption baseline to reflect updated data and to make other adjustments based on lessons learned from implementation of the hydrofluorocarbon phasedown program thus far, including proposing to: codify the existing approach of how allowances must be expended for import of regulated substances; revise recordkeeping and reporting requirements; and implement other modifications to the existing regulations.

FTC Trade Regulation Rule on the Use of Reviews and Endorsements; Advance notice of proposed rulemaking; request for public comment (Drugs/Medical Devices/Dietary Supplements) .

Comments due to FTC by January 9, 2023.

The FTC (the "Commission") proposes to commence a rulemaking proceeding to address certain deceptive or unfair uses of reviews and endorsements. The Commission is soliciting written comment, data, and arguments concerning the need for such a rulemaking to prevent unfair or deceptive marketing utilizing reviews and endorsements. In addition, the Commission solicits comment on how the Commission can ensure the broadest participation by affected interests in the rulemaking process.

FTC Unfair or Deceptive Fees Trade Regulation Rule Commission Matter No. R207011; Advance notice of proposed rulemaking; request for public comment .

Comments due to FTC by January 9, 2023.

The FTC ("Commission") proposes to commence a rulemaking proceeding to address certain deceptive or unfair acts or practices relating to fees. The Commission is soliciting written comment, data, and argument concerning the need for such a rulemaking to prevent persons, entities, and organizations from imposing such fees on consumers.

- **Public Meetings**
  NIH National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments; Notice (Drugs/Medical Devices/Dietary Supplements)

  Public Meeting: **December 15, 2022** (*virtual meeting*)

  Registration to make oral comments should be completed at https://ntp.niehs.nih.gov/go/165 due by **December 8, 2022**. Registration is not required to view the virtual meeting; the URL will be provided at https://ntp.niehs.nih.gov/go/165 the day before the meeting.

  Written comments due to NTP by **December 8, 2022**. Written public comments should be submitted through the meeting web page.

This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. The preliminary agenda, registration, and other meeting materials will be available at https://ntp.niehs.nih.gov/go/165 by **November 10, 2022** and updated one week before the meeting.

The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations on three contract concepts: Chemistry, Toxicology, and Pathology Support Services for the NIEHS. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (https://ntp.niehs.nih.gov/go/165) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

Non-FR Info – for your awareness only

Drugs

- In Vitro Permeation Test Studies for Topical Drug Products Submitted in ANDAs
  - Draft Guidance

- FDA issues final guidance about multiple endpoints in clinical trials (for any relevance to R&D/switch programs)

- Drugs@FDA Data Files (update)

- Final Guidance: Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (Updated)

- Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials; Draft Guidance for Industry; Availability (for any potential relevance to R&D programs)
  - Draft Guidance

- FDA Clinical Investigator Training Course (CITC) 2022

- POSTPONED: November 18, 2022 Joint Meeting of the Nonprescription Drugs Advisory Committee and the Obstetrics, Reproductive and Urologic Drugs Advisory Committee Meeting Announcement (

- Mott Poll Report: Parent actions around expired and leftover medicine in the home

- Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers (for any potential relevance to R&D/switch programs)
  - Draft Guidance

- S1B(R1) Addendum to S1B Testing for Carcinogenicity of Pharmaceuticals
  - Final Guidance

- CDER Conversation: FDA's Final Guidance on Carcinogenicity Testing of Pharmaceuticals
- Drugs@FDA Data Files (updated)
- Draft Guidance: Assessing User Fees Under the Over-the-Counter Monograph Drug User Fee Program
- The Drug Supply Chain Security Act (DSCSA) Implementation and Readiness Efforts for 2023 (for relevance to CHPA members subject to DSCSA)
- 14th Annual Sentinel Initiative Public Workshop
- CDER Conversation: FDA's Final Guidance on Carcinogenicity Testing of Pharmaceuticals
- 14th Annual Sentinel Initiative Public Workshop
- Competitive Generic Therapy Approvals (updated)
- Activities Report of the Generic Drugs Program | GDUFA II Quarterly Performance (Updated)
- Activities Report of the Generic Drug Program | FDARA Title VIII Sections 807 and 805 (Updated)
- M10 Bioanalytical Method Validation and Study Sample Analysis
  - Final Guidance

Medical Devices

- FDA Roundup: October 21, 2022
- At-Home OTC COVID-19 Diagnostic Tests .
- Do Not Use Certain Mighty Bliss Electric Heating Pads Due to Risk of Injury: FDA Safety Communication
- Whele LLC Announces National Voluntary Recall of Mighty Bliss Electric Heating Pad Due to Product Safety Concerns (does not involve a CHPA member)
- Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions
  - Final Guidance
- Third Party Review Organization Performance Report - FY2022, Q4

- Digital Health Research and Partnerships

  - COVID-19 Test Development and Review: FAQs on Testing for SARS-CoV-2 (Updated)
  - Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2 (Updated)
  - Virtual Public Workshop - CDRH Industry Basics: Understanding Risk with Medical Devices - November 15, 2022
  - Evaluation of Automatic Class III Designation (De Novo) Summaries (DEN200046, DEN210024 and DEN210034 added)
  - Breakthrough Devices Program (Updated)

- In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2 (Updated)

- CDRH Petitions (includes on standardizing the naming of hearing aid features & developing rating system using ANSI standards)

  - CDRH Petitions (Updated)
  - Do Not Use Infant Head Shaping Pillows to Prevent or Treat Any Medical Condition: FDA Safety Communication
  - CDRH Learn (Updated)
    - Specialty Technical Topics - Presentation and Transcript: Clinical Decision Support Software Final Guidance - October 18, 2022
    - In Vitro Diagnostics - Presentation and Transcript: COVID-19 and and Monkeypox Test Development and Validation Virtual Town Hall Series - October 26, 2022

- Revised Emergency Use Authorizations: Pixel by LabCorp COVID-19 Test Home Collection Kit (Laboratory Corporation of America (LabCorp))

- Virtual Town Hall Series - Test Development and Validation During Public Health Emergencies (Monkeypox and COVID-19) - November 9, 2022

- Activities to Support Medical Device Innovators (Updated)

Dietary Supplements

- Manufactured Food Regulatory Program Standards 2022 Updates (for relevance to dietary supplements)

- MFRPS 2022

Cross-category/General Interest

- FDA Roundup: October 25, 2022 (Drugs/Medical Devices)

- Webinar - Computer Software Assurance for Production and Quality System Software Draft Guidance (Drugs/Medical Devices) .

- Table of Pharmacogenetic Associations (Updated) (for any potential relevance to R&D/switch programs) (Drugs/Medical Devices)

- FDA Continues to Advance Medicines for Children (for any potential relevance to R&D/switch/PREA/BPCA activities) (Drugs/Medical Devices)

- FDA Roundup: October 28, 2022 (Drugs/Medical Devices/Dietary Supplements)

- Virtual Public Workshop - CDRH Industry Basics: Understanding Risk with Medical Devices (Drugs/Medical Devices)

- NIH Know the Science of Complementary Health Approaches: What the Science Says (includes reference to OTC drugs) (Drugs/Dietary Supplements)
- NIH Know the Science

- Medical Device Shortages During the COVID-19 Public Health Emergency (Updated) (Drugs/Medical Devices)

- MedSun Newsletter - November 2022 (includes several meetings that might be useful for R&D/switch programs) (Drugs/Medical Devices)

- FDA Roundup: November 1, 2022 (Drugs/Medical Devices/Dietary Supplements)

- 11/1/2022 - FDA Proposes Increase in Color Certification Fees (for relevance to drugs & dietary supplements)

- Evaluation of Automatic Class III Designation (De Novo) Summaries (for any potential R&D/switch programs) (Drugs/Medical Devices)

- FDA Roundup: November 4, 2022 (Drugs/Medical Devices/Dietary Supplements)