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*Summary Excerpts from Select *Federal Register* Notices for CHPA OTC Voice
Week of April 5, 2021

Drugs

Rulemaking

- FDA Electronic Import Entries; Technical Amendments; Final rule; technical amendments
    - Rule effective: **April 1, 2021**
- FDA Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs; Corrections; Final rule; correcting amendments
    - Rule effective: **April 1, 2021**

Public Meetings

- FDA Food and Drug Administration Science Forum 2021; Public Workshop; Notice of public workshop
    - Public Workshop: **May 26-27, 2021** (*virtual event*)
    - Registration to participate must be completed by **5:00 pm ET on May 21, 2021**, by visiting https://www.fda.gov/scienceforum. There is no charge to participate.

Medical Devices

Rulemaking

- FDA Medical Devices; Technical Amendments; Final rule; technical amendments
    - Rule effective: **April 1, 2021**

Dietary Supplements

Info Collection Notice

- FDA Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Allergen Labeling and Reporting; Notice
    - Comments and recommendations on the info collection due to FDA by **May 6, 2021**.

- Subject: Food Allergen Labeling and Reporting OMB Control Number 0910-0792--Extension

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

Cross-category

Guidances (Draft/Final)

- https://www.govinfo.gov/content/pkg/FR-2021-03-31/pdf/2021-06567.pdf CPSC Notice of Availability: Proposed Guidance on Alternative Test Methods and Integrated Testing Approaches; Notice of availability

    - Comments due to CPSC by **June 14, 2021**.

    The CPSC (or Commission) is announcing the availability of a document titled, "Proposed Guidance for Industry and Test Method Developers: CPSC Staff Evaluation of Alternative Test Methods and Integrated Testing Approaches and Data Generated from Such Methods to Support FHSA Labeling Requirements." The Commission requests comments on the proposed guidance.

    Proposed Guidance

Regulatory Information/Comment Opportunities

- HHS Regulatory Agenda; Semiannual Regulatory Agenda

    The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

Public Meetings

- Dept. of Commerce International Trade Administration Advisory Committee on Supply Chain Competitiveness: Notice of Public Meetings; Notice of open meeting

    - Public Meeting: **April 22, 2021** (*via Webex*)

    - Please contact richard.boll@trade.gov for participation information.

    - Written comments to the Committee may be submitted any time before and after the meeting. Those wishing to submit written comment for Committee consideration before and during this meeting

should email them to richard.boll@trade.gov by **5:00 pm ET on April 15, 2021**. Comments received **after April 15, 2021**, will be distributed to the Committee but may not be considered at the meeting.

- FDA Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting; Notice

    - AdCom Meeting: **May 11-12, 2021** (*virtual only; part of the meeting will be closed to the public*)

    - The meeting will be webcast both days and will be available at the following link: https://collaboration.fda.gov/nctr1000/.

    - Request to make oral remarks should be made by **April 26, 2021**.

    - FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at https://collaboration.fda.gov/nctr1000/, and the recording plus transcript will be posted on FDA's website after the meeting. Background material is available at https://www.fda.gov/advisorycommittees/advisory-committee-calendar.

Non-FR Info – for your awareness only

Drugs

- Generic Drugs Forum 2021: Lifecycle of a Generic Drug
- FY 2021 Generic Drug Science and Research Initiatives Public Workshop
- Coronavirus (COVID-19) Update: April 2, 2021
- A-S Medication Solutions Issues Voluntary Nationwide Recall of Acetaminophen Extra Strength Tablets Contained in Health Essentials Kits Due to Mislabeling
- GDUFA III Reauthorization Negotiation Sessions
- Development of Abbreviated New Drug Applications During the COVID-19 Pandemic – Questions and Answers Guidance for Industry
    - Final Guidance

Medical Devices

- Coronavirus (COVID-19) Update: FDA Continues to Advance Over-the Counter and Other Screening Test Development

- Accelerating Medical Device Innovation with Regulatory Science Tools

- CDRH Industry Basics Workshop: Consensus Standards and the Accreditation Scheme for Conformity Assessment (ASCA) Pilot

- Traumatic Brain Injury: What to Know About Symptoms, Diagnosis, and Treatment

- Presentation and Transcript added to Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation - March 24, 2021

- Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation - April 7, 2021

- New Emergency Use Authorizations (*related to OTC use COVID-19 test kits*)
  - QuickVue At-Home OTC COVID-19 Test (Quidel Corporation)
  - BinaxNOW COVID-19 Antigen Self Test (Abbott Diagnostics Scarborough, Inc.)
  - BinaxNOW COVID-19 Ag Card 2 Home Test (Abbott Diagnostics Scarborough, Inc.)
  - BinaxNOW COVID-19 Ag 2 Card (Abbott Diagnostics Scarborough, Inc.)

- Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2

Dietary Supplements

- Guidance for Industry: Enforcement Policy for Providing an Acceptable Unique Facility Identifier (UFI) for the 2020 Food Facility Registration Biennial Renewal Period
  - https://www.fda.gov/media/143997/download Guidance

- FDA Extends Flexibility for Unique Facility Identifier Requirement for Food Facility Registration through December 2022

- HI-TECH Pharmaceuticals Issues Allergy Alert on Various APS Isomorph 28 Products and iFORCE Nutrition Mass Gainz Dietary Supplements Due to Possible Undeclared Milk, Eggs, Wheat and Soy

Cross-category/General Interest

- Coronavirus (COVID-19) Update: March 30, 2021

  - FDA COVID-19 Response At-A-Glance Summary

- Nuri Trading LLC Issues Voluntary Nationwide Recall of Shogun-X 7000, Thumbs Up 7 (Black) 25K, Thumbs Up 7 (White) 11K, 69MODE Blue 69, Due to the Presence of Undeclared Tadalafil, Sildenafil, and/ or Vardenafil

- Ummzy LLC Issues Voluntary Nationwide Recall of Thumbs up 7 Red 70K, Shogun-X 15000mg, and Krazy Night Due to the Presence of Undeclared Tadalafil Sildenafil & Vardenafil

- Coronavirus (COVID-19) Update: FDA Makes Two Revisions to Moderna COVID-19 Vaccine Emergency Use Authorization to Help Increase the Number of Vaccine Doses Available (COVID-19)

- NANA Collection LLC Issues Voluntary Nationwide Recall of PremierZen Platinum 5000 & Triple SupremeZen Gold 3500 Due to Presence of Undeclared Drug Tadalafil and Sildenafil

- QMART Issues Voluntary Nationwide Recall of IMPERIAL Gold 2000, PremierZEN Extreme 3000, BURRO en PRIMAVERA 60000 & IMPERIAL Platinum 2000 Due to Presence of Undeclared Sildenafil and/or Tadalafil