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*Summary Excerpts from Select *Federal Register* Notices for CHPA OTC Voice
Week of March 29, 2021

Drugs

Regulatory Information/Comment Opportunities

- FDA Fee Rates Under the Over-the-Counter Monograph Drug User Fee Program for Fiscal Year 2021; Notice

    - The new fee rates are for the period from **October 1, 2020, through September 30, 2021**.

      FDA (or the Agency) is announcing the fee rates under the Over-the-Counter (OTC) Monograph Drug user fee program for fiscal year (FY) 2021. On March 27, 2020, new provisions were added to the FD&C Act by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which authorize FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests. FDA refers to the OTC Monograph Drug user fee program as "OMUFA" throughout this document. This notice publishes the OMUFA fee rates for FY 2021.

      Table 1.--Fee Schedule for FY 2021
      Fee Category FY 2021 Fee Rates
      OMOR
      Tier 1 $500,000
      Tier 2 $100,000

      Facility Fees
      MDF $20,322
      CMO $13,548

- FDA Request for Nominations for Individuals and Consumer Organizations for Advisory Committees; Notice

    - Consumer organizations interested in participating in the selection process should notify FDA by **April 26, 2021**.
    - Nomination materials for prospective candidates are due to FDA by **April 26, 2021**. Nominations will be accepted for current vacancies and for those that will or may occur through **December 31, 2021**.

Cross-category

Guidances (Draft/Final)

- CPSC Notice of Availability: Proposed Guidance on Alternative Test Methods and Integrated Testing Approaches; Notice of availability Notice

  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 Notice

  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.

Non-FR Info – for your awareness only

Drugs

- Durisan Hand Sanitizer Recall Due to Microbial Contamination
- Drug Safety Oversight Board (DSOB) Meeting February 18, 2021
- FDA updates on hand sanitizers consumers should not use
- FDA Drug Safety Podcast: FDA warns that abuse and misuse of the OTC nasal decongestant propylhexedrine can lead to serious harm

Medical Devices

- Medical Device Regulatory Science Research Programs Conducted by OSEL
- In Vitro Diagnostics EUAs
- New CDRH Learn Modules: Introduction to the MDSAP Program and Overview of the MDSAP Process

- Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2 (STS Lab Holdco (a subsidiary of Amazon.com Services LLC))

Cross-category/General Interest

- Learn More About COVID-19 Vaccines From the FDA

- AHRQ Surveillance Report Now Available:
  Living Systematic Review on Cannabis and Other Plant-Based Treatments for Chronic Pain – Quarterly Progress Report: February 2021 (Surveillance Report, released on March 24, 2021) (Drugs/Dietary Supplements)

  This is the second progress report for an ongoing living systematic review on plant-based treatments for chronic pain. The ensuing systematic review will synthesize evidence on the benefits and harms of cannabinoids and other plant-based compounds (PBCs) such as kratom used to treat chronic pain, addressing the impact on pain and function, as well as concerns about adverse effects, abuse, misuse, dependence, and addiction.

- Coronavirus (COVID-19) Update: March 26, 2021

- Namoo Enterprise LLC Issues Voluntary Nationwide Recall of PremierZen Black 5000 Due to the Presence of Undeclared Sildenafil and Tadalafil

- Antoto-K Issues Voluntary Nationwide Recall of Thumbs Up 7 Red 70K Due to the Presence of Undeclared Sildenafil and Tadalafil

- Public Notifications:
  - Yin-Yang Essence Men Power contains hidden drug ingredients
  - Furious X 1350 contains hidden drug ingredients
  - Zing Plus contain hidden drug ingredient