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Docket FDA-2022-D-2059

November 7, 2022

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Providing Over-the-Counter Monograph Submissions in Electronic Format; Draft Guidance for Industry; FR Vol. 87, No. 187, 58802-3, September 28, 2022; Industry Comments

Dear Sir or Madam:

The Consumer Healthcare Products Association[1] (CHPA) is pleased to submit these comments on the draft guidance issued by U.S. Food and Drug Administration (FDA or the Agency) on Providing Over-the-Counter Monograph Submissions in Electronic Format, Draft Guidance for Industry. This guidance provides information on providing electronic submissions to FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act). For more than 141 years, CHPA has served as a vital advocate for the consumer healthcare products industry. A member-based trade association, CHPA represents the leading manufacturers and marketers of OTC medical products. Our members provide millions of Americans with safe, effective, and affordable therapies to treat and prevent many common ailments and diseases.

CHPA appreciates and acknowledges that the Agency has met it obligations under Section 505G(1)(3) to provide a guidance intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act. The draft document provides recommendations and other information on how sponsors can send such OTC monograph submissions to FDA in electronic format.

After a thorough review of this draft guidance document, CHPA is submitting the following comments that would further assist its members to better understand the electronic submission pathways and choices:

1. Use of Comprehensive Visual Charts or Tables for each Submission Pathway Based on Type of Document.
    a. CHPA acknowledges that the Agency has described submission requirements via two types of portals: a) CDER NextGen Portal and b) OTC Monograph@FDA Portal. However, the guidance lacks sufficient details as to the specific type of

[1] The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing the leading manufacturers and marketers of consumer healthcare products, including over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices. CHPA is committed to empowering self-care by ensuring that Americans have access to products they can count on to be reliable, affordable, and convenient, while also delivering new and better ways to get and stay healthy.
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document allowed for each portal. The guidance document does however contain a statement (line 72, footnote 15) that sponsors should use the electronic portal as specified by instructions in the OTC Monograph@FDA portal. Our recommendation is to provide a list of what documents are acceptable for each portal.

i. The Agency should include visual tables that list each type of document allowed for each portal. CHPA members realize that additional types of documents may be developed in the future, but those documents could be added at a later point in time. When the final guidance is published, the proposed reference table or chart for documents allowed for each portal should be as accurate as possible.

2. Non-Secure Sign-On Processes and Options
    a. CHPA recommends that the Agency provide in writing any limitations, as well as instructions on how to proceed when a new user creates a new account in the CDER Nextgen portal with a non-secure email. CHPA recognizes that non secure emails present certain challenges and limitations on what can be filed.

    b. CHPA recommends that the Agency include in this guidance document any established workarounds and methods such as the use of secureEmail@fda.hhs.gov when an email that contains confidential information is not secure. Including this type of information would provide a more holistic approach about sending any type of documents to the Agency.

3. Specifications on Agency File Limitations
    a. CHPA recommends that the Agency publish the current file size limitations within this guidance document and provide instructions for alternative solutions before the sponsor contacts the EDMS support staff. (Refer to line 102). Sponsors should know in advance if their file sizes will need additional CDER assistance prior to submission. A submission rejection because of file size limitation may lead to confusion and may ultimately cause the sponsor to miss their submission timeline date.
    b. CHPA requests that the Agency provide information on how sponsors can submit compressed files to manage the file size limitation.
    c. CHPA requests that the Agency provide written information and instructions back to the sponsor as to why any uploaded file fails to upload for both portals.

4. CDER NextGen Website & DUNs Information
    a. CHPA recommends that written instructions should be included on the website to assist sponsors or individuals who do not have a DUNs number. Currently, the website does not provide sufficient information of what to enter when a sponsor or individual needs to create an account and does not have a DUNS number.

5. File Naming Conventions
    a. CHPA recommends that the Agency provide future information in subsequent guidance on file naming conventions.

CHPA appreciates the opportunity to provide input for Agency consideration as it works to finalize this guidance. Please feel free to contact me if there are any questions.

Sincerely,

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