January 22, 2019   submitted electronically via www.regulations.gov

Dockets Management Staff (HFA-305)
Food and Drug Administration

Chris Wheeler
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 51, Rm. 3330
Silver Spring, MD 20993

Re: **Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments**
Docket No. FDA-2018-N-3017; 83 Fed. Reg. 58574 (November 20, 2018)

Dear Dr. Wheeler:

In the November 20, 2018, *Federal Register*, the Food and Drug Administration invited comments on the above-referenced proposed framework for regulating software applications disseminated by or on behalf of drug sponsors for use with one or more of their prescription drugs.

The Consumer Healthcare Products Association (CHPA), founded in 1881, is the national trade association representing manufacturers and distributors of over-the-counter (OTC) medicines, dietary supplements, and consumer medical devices in the United States. Our mission is to empower self-care by preserving and expanding choice and availability of consumer healthcare products. We understand the proposed framework in the notice is limited to prescription drugs. We have an interest in this subject, however, since we could foresee the policies described have utility for nonprescription drugs under new drug applications (including abbreviated new drug applications) or having implications as FDA works on an anticipated proposed rule on innovative approaches to nonprescription drug approvals. For instance, items that correlate to additional, mandatory conditions for safe use described in FDA's Draft Guidance for Innovative Approaches to Switch (published July 2018), could have software output. There are already examples of software applications in the market for OTC medicines. For instance, personalized behavioral support with FDA-approved smoking cessation medicines can improve a smoker's chance of quitting. Or a software application with visual elements can interact with a child to help parents teach their children better tooth brushing habits (which of course involve both a device, the toothbrush, and a drug, the anti-cavity dentifrice).

General comments.

Labeling v. other approaches. As a threshold matter, we note that promotional messages for consumer healthcare products are generally regulated as advertising and therefore are under the primary jurisdiction of the Federal Trade Commission. We therefore are not commenting on promotional labeling aspects of the proposed prescription drug framework. An open question for FDA to consider in the framework is whether the expansive approach to labeling described unduly limits opportunities for drugs with companion devices. We believe that only software output that includes safety or effectiveness claims or dosing and administration information for a drug should be regarded as labeling and thus prescription drug use related software output.

Related to this, more clarification would be useful on how FDA will approach software classifications and combination use determinations.

Just as one hypothetical example: Drug maker Z is working with software firm A to market an app related to a frequently concomitant condition in patients currently taking a Z's approved drug. Would FDA expect a software as a medical device submission (510(k) or de novo) from software firm A to CDRH in addition to a CDER drug application from Z regarding introduction of the drug-use related software and labelling change? Are there opportunities to streamline the potential duplication of this process?

Software outputs as required labeling. Where software outputs *are* required labeling, we appreciate FDA's examples of outputs being considered within an overall labeling system, rather than independently. In other words, we support a view that the software output could be additive or supplementary (i.e., not inconsistent). For example, if the output constituted labeling on risk information or dosage adjustments, benefit information could come from another form of labeling, including on the package label itself.

Sponsor v. third party software. The notice references on several occasions that software developed by non-pharmaceutical third parties are not covered by the proposed framework. In developing draft guidance, we encourage the agency to provide perspectives on what level of business relationships or cooperation would remain appropriate before the third party's software is no longer "independently developed," keeping in mind the broad range of collaboration between drug sponsors and other innovators. In other words, how would FDA distinguish between a product-specific direct relationship versus non-product-specific, indirect business relationships for purposes of the framework? For instance, we could easily envision situations where drug maker Z is working on projects with software firm A that are unrelated to the specific drug under the framework, but A on its own had specific software about a disease state that happens to be treated by Z's drug. A collaboration could even involve multiple drug sponsors. In contrast, FDA's notice only provides very black and white examples of when a third party's software is no longer "independently developed," for example when Z disseminates A's software directly, or when A does so directly on Z's behalf. Further guidance between these two extremes would be helpful, including examples of the kinds of varied collaborations that are taking place across the industry, to help sponsors assess whether software is or is not "independently" developed.

Pre-cert program. How does FDA envision the proposed framework inter-relating with the CDRH software pre-certification program?

Specific comments.

Finally, on three of FDA's specific questions:

1. Does the approach foster innovation? The facts that the agency is providing greater guidance on how software output would be reviewed and is seeking to take pragmatic approaches offer opportunities for innovation. We commend the agency for that. We note that if labeling output does change, and the output is FDA-required labeling, the change should be evaluated under existing regulations for labeling updates (i.e., annual report, CBE, or prior approval supplement).

3. Does it preserve FDA's ability to ensure existing drug labeling requirements are met? CHPA believes that the framework preserves FDA's ability to ensure drug labeling requirements are met where, as noted above, software outputs are required labeling, and FDA considers outputs as a part of a drug's entire labeling system, rather than independently with any given element required to carry all labeling. We read the notice as supporting a view that the software output could be additive or supplementary (i.e., not inconsistent). For example, if the output constituted labeling on risk information or dosage adjustments, benefit information could come from another form of labeling, including the package label itself.

7. Is FDA's approach that sponsors are responsible for software's reliable production of output sufficient? Yes, sponsors should be responsible for the reliable production of outputs from their software. The proposed framework would support real time software updates (a security patch, for instance, or an update to run on a new version of a third party's operating system) that do not alter output. This is an appropriate approach.

Thank you for the opportunity to provide these views. Please contact us at any time if we can provide additional information.

Sincerely,

/s/

David C. Spangler
Senior Vice President, Policy.
  & General Counsel
e: dspangler@chpa.org

Rx-related_software_comments-to-FDA-f22Jan2019