CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
founded 1881

Submitted electronically via email to Sean Casey and Michelle Bacon

November 22, 2016

The Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Re: Request for Comments on the Office of Management and Budget Information Technology Modernization Initiative. 81 *Fed. Reg.* 74817-74818 (October 27, 2016)

To Whom It May Concern:

The Consumer Healthcare Products Association (CHPA[1]) submits the following comments to the U.S. Office of Budget and Management (OMB) in response to a request for public input on a draft memorandum titled "Information Technology Modernization Initiative." The report was released in a recent *Federal Register* notice.[2] General suggestions for future improvements to the aging Federal government technology infrastructure are provided below.

On behalf of its interested members, CHPA recommends that any modernization of the government's technology infrastructure consider integration of the various information technology (IT) platforms, both within a particular federal agency and as well as across different regulatory authorities as appropriate. Allowing intra- and inter-agency database communication could minimize or eliminate redundancy where the same or similar information is being collected by multiple divisions and/or Federal regulatory bodies. Appropriate validation procedures could be implemented to ensure data quality.

One example of a current redundancy affecting regulatory compliance for the over-the-counter (OTC) or nonprescription medicine industry is related to drug listing and OTC medicines imported into the U.S. As required by the Federal Food, Drug & Cosmetic Act (FD & C Act), sponsors must enter their OTC drug products into the U.S. Food and Drug Administration's (FDA) electronic drug registration and listing system (eDRLS).[3] Many OTC medicines are imported from abroad for domestic sale and therefore, must be approved by the U.S. Customs department to enter the country.

FDA has an automated system for processing and determining admissibility for shipments of FDA-regulated products seeking to enter U.S. commerce which originate overseas. However, this database, the Operational and Administrative System for Import Support (OASIS) is not linked to the

[1] The Consumer Healthcare Products Association (CHPA) is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.
[2] *Federal Register* notice published on October 27, 2016 (81 *Federal Register*) 74817-74818). Accessed at https://www.gpo.gov/fdsys/pkg/FR-2016-10-27/pdf/2016-25948.pdf on November 7, 2016.
[3] See FDA website titled "Drug Registration and Listing System (DRLS and eDRLS). Access at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/drugregistrationandlisting/ucm2007058.htm on November 7, 2016.

eDRLS database despite being under the purview of the same regulatory agency (*i.e.,* U.S. FDA). As such, sponsors must complete additional data entry to ensure their products are cleared for importation in a timely manner. This inefficiency can lead to unnecessary duplication of work and to potential delays of OTC medicines at the border instead of being available to consumers who use these products as part of their overall healthcare regimen.

CHPA members also recommend any updated or new IT systems continue to allow for utilization of digital signatures (*i.e.,* electronic signatures) on official documents. Use of encrypted digital signatures enhances the security of these documents by minimizing the risk of tampering or forgery. However, any modernization of the Federal government's IT databases should ensure that the process to use digital signatures is user-friendly and not needlessly complex. There are currently some governmental agencies (*e.g.,* Internal Revenue Service (IRS), Social Security Administration (SSA)) with systems that allow companies to create a user identification and password which are used thereafter for their digital signatures. As updates to the overall Federal IT platforms are considered, the IRS and SSA procedures may serve as models for other governmental agencies with more complex methods to establish and use electronic signatures on documents (*e.g.* the U.S. FDA). Any IT platform must be able to utilize e–signatures such as those now permitted with pdf documents.

In general, new or revised IT systems should be designed to provide for full transparency and readability, be searchable, and easily accessible to the public when appropriate. OMB or the responsible governmental agency(ies) should consider piloting any proposed changes with relevant stakeholders prior to full-scale implementation.

We hope these comments are useful to OMB as it develops new policy to modernize the Federal government's IT system. Feel free to contact me should questions arise.

Sincerely,

Marcia D. Howard

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