



September 1, 2017

US Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852
via electronic submission

Subject: **Docket No. FDA-2017-D-2232** for "Product Identifier Requirements Under the Drug Supply Chain Security Act - Compliance Policy; Draft Guidance for Industry; Availability"

Dear Sir or Madam:

ISPE (the International Society for Pharmaceutical Engineering) would like to submit comments for the FDA draft guidance Product Identifier Requirements Under the Drug Supply Chain Security Act - Compliance Policy. The draft was reviewed by ISPE's technical sub-committee known as the Serialization Special Interest Group, which is comprised of individuals from pharmaceutical companies, CMPs, suppliers, and service providers.

ISPE wishes to acknowledge the FDA's recognition of Industry's concerns regarding stakeholder challenges with implementation of product identifier requirements due to: (1) a limited number of vendors that have experience to provide solutions related to information technology systems for data management or specific equipment for packaging or manufacturing lines, and (2) capabilities and readiness of contract facilities to perform manufacturing operations on behalf of the manufacturer.

ISPE is further pleased that the messages and dialogue with industry during its Pharmaceutical Serialization Workshops (held 8 – 9 May 2017 in Philadelphia) were recognized and that ISPE was able to facilitate an open forum for constructive dialogue regarding this matter between industry and regulators. ISPE remains committed through the expertise of its members to lend its expertise on this topic and will continue to engage industry and regulators through its education programs towards implementation.

General and specific comments on the draft are included in the following pages. We appreciate the opportunity to submit these comments for your consideration.

ISPE is a not-for-profit organization of individual members leading scientific, technical and regulatory advancement throughout the entire pharmaceutical lifecycle. The 18,000 members of ISPE are building solutions in the development and manufacture of safe and effective pharmaceutical and biologic medicines and medical delivery devices in more than 90 countries around the world. ISPE does not take political positions or engage in lobbying activities or legislative agendas.

Please do not hesitate to contact me if you have any questions.

Sincerely,

John E. Bournas
ISPE CEO and President



1) Key Messages

ISPE continues to support the need to be able to track prescription products through the supply chain and trace products care custody and control history to enhance patient safety and product security through the supply chain.

ISPE also supports the need for a delay in the enforcement of the provisions of section 582(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 360eee-1(b)(2) on the grounds that there is a limited number of vendors with the capabilities necessary for serialization readiness, and for contract manufacturing facility readiness.

ISPE supports the proposed the delay of enforcement and recognizes the change from the current proposed date of November 27, 2017 to November 27, 2018 for manufacturers to affix or imprint a product identifier, but suggests the Agency considers:

- a) A further delay of two years beyond November 27, 2018 for repackagers to engage only in transactions involving products that bear a product identifier (i.e. a compliance enforcement date of November 27, 2020 for repackagers).
- b) A commensurate delay in the parallel requirements for wholesale distributors compliance (i.e. a compliance enforcement date of November 27, 2020).
- c) The proposed incremental compliance enforcement time for dispensers (i.e. a compliance enforcement date of November 21, 2021).
- d) That a waiver/exception reporting system be implemented for those products introduced into commerce before November 27, 2018 which have not been serialized, which have not been consumed and have a shelf life in excess of November 27, 2020.

2) Background

ISPE has considerable experience with manufacturing and supply chain operations. Within the ISPE organization sub-teams have been formed and operating around serialization compliance with a specific view towards the complexities that serialization introduces.

It is the opinion of these sub-teams that the effects of an incomplete system and lack of guidance on implementation increase the risks associated with introducing serialization and have the ability to significantly increase drug shortages and cause a large amount of non-value-added work within pharmaceutical supply chains.

Most recently, ISPE held a Pharmaceutical Serialization Workshops event in May 2017, with FDA regulators present, that both highlighted and reinforced the pharmaceutical industry's lack of readiness for serialization, not only for the reasons published in the FDA Draft Guidance, but also due to lack of harmonized standards with other jurisdictions requiring serialization, lack of coordinated standards and guidance from national and international industry organizations, and the

difficulties associated with data management, reporting and communication. Many ex-US representatives were present at this conference and confirmed these concerns when similar regulations were promulgated in their respective jurisdiction.

Lastly, we would ask the FDA to consider that no guidance has yet been issued, and that this information is critical to the proper design, implementation and on-going proper operation of a fully integrated and interoperable product identifier system as required by the Drug Supply Chain Security Act (DSCSA).

3) Main Comments and Recommendations

The implementation of a full track and trace system impacts nearly all aspects of pharmaceutical supply operations. ISPE believe that the effort to implement a serialization system in the pharmaceutical manufacturing environment and supply chain has been underestimated by a number of operating/manufacturing companies and vendors and that the wide-reaching aspects of this implementation are only recently being understood. Further, the continual delays of the promulgation of regulations of (notably) the California Drug Quality and Security Act, which was then further preempted by this Federal DSCSA Regulation, has created an expectation by many in the industry that there will be continued delays to allow time for implementation.

The delay of enforcing manufacture compliance with product identifier requirements for a one-year period appears to be appropriate as it allows time for vendors and manufacturers to continue their progress in implementing serialization systems and controls, but in parallel to this effort, FDA should deliver the needed guidance for proper design, implementation and on-going management of products identifier data. Specifically, technical guidance should be issued regarding how product identifier data is requested, communicated and controlled. Further, the Agency should address who will have access to ePedigrees, and to what level will that access be granted.

ISPE does not agree with cascading the one-year enforcement delay as noted in lines 173 – 184 of the Draft Guidance. ISPE recommends that a two-year delay beyond November 27, 2018 for repackagers to engage only in transactions involving products that bear a product identifier (i.e. a compliance enforcement date of November 27, 2020 for repackagers) and suggests a commensurate delay in the parallel requirements for wholesale distributors compliance (i.e. a compliance enforcement date of November 27, 2020), and the proposed incremental compliance enforcement time for dispensers (i.e. a compliance enforcement date of November 21, 2021). The simple logic behind this recommendation is that many pharmaceutical products have a two-year expiry dating, and the two-year delay in enforcement will ensure these un-serialized products will be consumed before enforcement is enacted. Further for those products with a longer shelf life ISPE suggests that the FDA implement a waiver/exception reporting system to allow these products to be consumed, thereby minimizing any potential stock outs and drug shortages.

4) Recommendations summarized

- a) ISPE supports the proposed the delay of enforcement from the current proposed date of November 27, 2017 to November 27, 2018 for manufacturers to affix or imprint a product identifier,
- b) ISPE suggests the Agency considers a further delay of two years beyond November 27, 2018 for repackagers to engage only in transactions involving products that bear a product identifier (i.e. a compliance enforcement date of November 27, 2020 for repackagers).
- c) ISPE suggests a commensurate delay in the parallel requirements for wholesale distributors compliance (i.e. a compliance enforcement date of November 27, 2020), and the proposed incremental compliance enforcement time for dispensers (i.e. a compliance enforcement date of November 21, 2021).
- d) That a waiver system be implanted to allow un-serialized product in the that entered the supply chain before November 27, 2018 to be consumed
- e) The Agency should consider remediating its delayed planned implementation plan.

5) Concluding comments

ISPE wishes to thank the FDA for the opportunity to comment on this important complex matter and applauds the FDA's recognition of Industry's concerns regarding stakeholder challenges with implementation of product identifier requirements due to: (1) a limited number of vendors that have experience to provide solutions related to information technology systems for data management or specific equipment for packaging or manufacturing lines, and (2) capabilities and readiness of contract facilities to perform manufacturing operations on behalf of the manufacturer.