January 3, 2018

BY ELECTRONIC FILING http://www.regulations.gov, Dkt. No. FDA-2014-D-0609

From: Pharma & Biopharma Outsourcing Association
10 Alta Vista Dr.
Ringwood, NJ 07456
Tel: 201-788-7994

To: Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Comments from Pharma & Biopharma Outsourcing Association (PBOA) on Docket No. FDA-2014-D-0609 for "*Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*".

Dear Sir/Madam,

On behalf of the Pharma & Biopharma Outsourcing Association ("PBOA"), a trade association representing Contract Manufacturing Organizations and Contract Development & Manufacturing Organizations ("CDMOs"), I am pleased to offer feedback on the recent notice, "*Submission for Office of Management and Budget Review; Comment Request; Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*" and updated estimates of effort to implement DSCSA. Our Serialization Working Group, composed of serialization leads from more than a dozen of our member companies, has discussed this notice and outlined feedback below for your consideration.

We are concerned about the dramatic downward revision to the number of anticipated notifications for illegitimate products.

- The total number of respondents and the ratio of responses raises questions about the 2016 and 2017 data. There are more than ten times as many pharmacies (69,000) as manufacturers/repackagers (6,500) and greater than thirty times more than wholesale distributors (2,230) in the supply chain. Based on the data collected and the calculation presented:
    - 80% of notifications are expected to come from manufacturers; 120 out of 6,500 are expected to have one notification each year based on '16/'17 data (1.8%).
    - 15% of responses are predicted to come from wholesale distributors; 22 out of 2,230 sites (0.98%).
    - 5% of responses are predicted from Pharmacies; 8 out of 69,000 sites (0.01%).

Collectively, attrition of the failure rate reported across the supply chain in 2016 and 2017 implies either a very efficient control system across the industry or may indicate that pharmacies are not reporting correctly.

- According to the calculation presented, FDA anticipates receiving 8 responses from 69,000 locations, if each pharmacy only handles 1,000 packages per year, this represents an overall defect rate of 0.115 per million opportunities or a 0.0000115% failure rate. Since most pharmacies handle considerably more than 1,000 packages per year, the true defect rate in delivering pharmaceutical products to patients approaches zero. We are concerned that these notification rates are grossly underestimated.

- While this Agency Collection of Information is only intended to cover the burden of notifications, we would like to note that investigations leading to the disposition of a suspect products are not included. These investigations will likely span multiple departments and, in many cases, multiple companies to investigate the claim, assess the impact, and develop countermeasures. And as the effort calculated by FDA in this estimate is only for confirmed illegitimate product requiring notification to supply partners, we note that it further neglects to capture the effort to investigate product that is ultimately overturned.

PBOA appreciates the opportunity to review and provide comments pertaining to this notification. We look forward to working with FDA on its continued efforts to implement the DSCSA.

Thank you for considering our views.

Respectfully,

Christopher Verbicky

Chris Verbicky, Ph.D., M.B.A.
Director, Scientific and Regulatory Affairs
PBOA

PBOA Member Companies

3M Drug Delivery Systems
Ajinomoto Bio•Pharma Services
Alcami
Avid Bioservices
Avista Pharma Solutions
Afton Scientific
Baxter BioPharma Solutions
Cambrex
Catalent Pharma Solutions
CMIC CMO USA, Inc.
Coating Place, Inc.
CPC - Contract Pharmacal Corp.
DPT, a Mylan Co.
Grand River Aseptic Manufacturing
Groupe PARIMA
iBio Inc.
IDT Biologika
Jubilant HollisterStier
Lyophilization Services of New England (LSNE)
Metrics Contract Services
Mission Pharmacal/ProSolus Pharma
Particle Sciences, a Lubrizol Co.
Patheon Inc., part of Thermo Fisher Scientific
PCI Pharma Services
Pfizer CentreOne
Piramal Pharma Solutions
Pharma Packaging Solutions
Renaissance Lakewood
Tapemark Inc.
TEDOR Pharma
Therapure Biomanufacturing