CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

# WEBINARS

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Version 3 – Updated September 3, 2022

# Reporting Drug Amount Under Section 510(j)(3) of the FD&C Act

## September 8, 2022

*Add Event to Your Calendar*

# AGENDA

All times are Eastern (EST UTC-4)

*View Start Time on World Clock*

9:30 – 9:40

### SBIA Welcome and Administrative Overview

**Forest "Ray" Ford, PharmD, BCPS**
*Captain,* United States Public Health Service
Small Business, and Industry Assistance (SBIA)
Division of Drug Information (DDI) | Office of Communications (OCOMM) | CDER

9:40 – 9:45

### Opening Remarks

**Jennifer Forde**
*Regulatory Counsel*
Office of Regulatory Policy

9:45 – 9:55

### Drug Amount Reporting Regulatory Background

Drug amount reporting program regulatory background and associated FDA implementation activities.

**Jennifer Forde**
*Regulatory Counsel*
Office of Regulatory Policy

9:55 – 10:05

### Registration and Listing Regulatory Background and Requirements

Overview of registration and listing requirements that pertain to the drug amount reporting program.

**Leyla Rahjou-Esfandiary**
*Lead Consumer Safety Officer*
Office of Compliance

10:05 – 10:25

### Purpose of Drug Amount Reporting

Review of FDA's use of data submitted under the drug amount reporting program.

**Matthew Rosenberg**
*Economist*
Office of Strategic Programs

10:25 – 10:40

## Basic Framework for Reporting

Review of structure and content of drug amount reports.

**Jennifer Highland**
*Operations Research Analyst*
Office of Pharmaceutical Quality

10:40 – 11:10

## Questions & Answer Panel

**Jennifer Forde, Leyla Rahjou-Esfandiary, Matthew Rosenberg, Jennifer Highland**

**11:10 – 11:30: BREAK**

11:30 – 12:15

## CARES Drug Amount Report Examples

Review drug amount report examples and NextGen Portal best practices for successful report submission.

**Obinna Ugwu-Oju**
*Division Director*
Office of Pharmaceutical Quality

**Edward Hallissey**
Office of Strategic Programs

12:15 – 12:30

## Questions & Answer Panel

**Obinna Ugwu-Oju, Edward Hallissey,** and **Daniil Graborov**

**12:30 – 1:00: LUNCH BREAK**

All times shown are Eastern (EST UTC-4)

1:00 – 1:20

## CARES Act OTC Drug Volume Reporting - Perrigo

Review of drug amount reporting from the perspective of a large OTC consumer self-care drug product manufacturer, including obstacles overcome, accomplishments, and insights gained during this compliance effort.

**Kim Armstrong**
*Associate Director*
Perrigo OTC Regulatory Affairs Operations

1:20 – 1:40

## Johnson & Johnson Consumer Inc. - CARES Act Drug Amount Reporting - OTC Products

Describe roadmap in meeting CARES Act drug amount guidance from Johnson & Johnson Consumer Inc.'s perspective, including the company's interpretations, roadblocks, and suggestions gained from their learning experiences.

**Gracy Tirado**
*Associate Director RA Compliance*
Johnson & Johnson Consumer Inc.

**1:40 – 1:55: BREAK**

1:55 – 2:15

## Reporting Drug Amounts Under Section 510 of the FD&C Act as an Authorized Agent and cGMP Consultant

Included topics for this presentation are: 1) decoding guidance, 2) identifying roles and responsibilities as a consultant and authorized agent, 3) a general description of a few client and manufacturing scenarios, 4) general experience of reporting drug volumes in the CDER NextGen Portal, 5) challenges, and 6) recommendations for industry and FDA.

**Ken Coleman ("KC") Stevenson II**
*VP of Regulatory*
Ceutical Laboratories, Inc.

2:15 – 2:35

## Drug Volume Reporting: Industry Perspective

A summary of the experience of putting together and submitting drug volume reporting data. Presentation includes topics for clarification, and some suggestions for improvement.

**Ben Harpster**
*QA Compliance Manager*
GlaxoSmithKline

2:35 – 3:05

## Questions & Answer Panel

**Jennifer Forde, Jennifer Highland, Obinna Ugwu-Oju, Ed Hallissey, Daniil Graborov**

3:05 – 3:10

## Closing Remarks

**Jennifer Forde**
*Regulatory Counsel*
Office of Regulatory Policy

**3:10: WEBINAR ADJOURN**

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