CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

WEBINARS

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Version 2 – Updated August 28, 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

Brenda Stodart, PharmD, MS, BCGP, RAC-US
Captain, United States Public Health Service
Director, 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

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

Kim Armstrong, Gracy Tirado, KC Stevenson, Ben Harpster

3:05 – 3:10

Closing Remarks

Jennifer Forde
Regulatory Counsel
Office of Regulatory Policy

3:10: WEBINAR ADJOURN

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