Regulatory Affairs, GDD

Global Labeling
Compliance & Artwork

Structured Product Labeling (SPL) at Novartis

Corey Schmidt, Global Labeling Systems and Compliance Team Lead

NOVARTIS

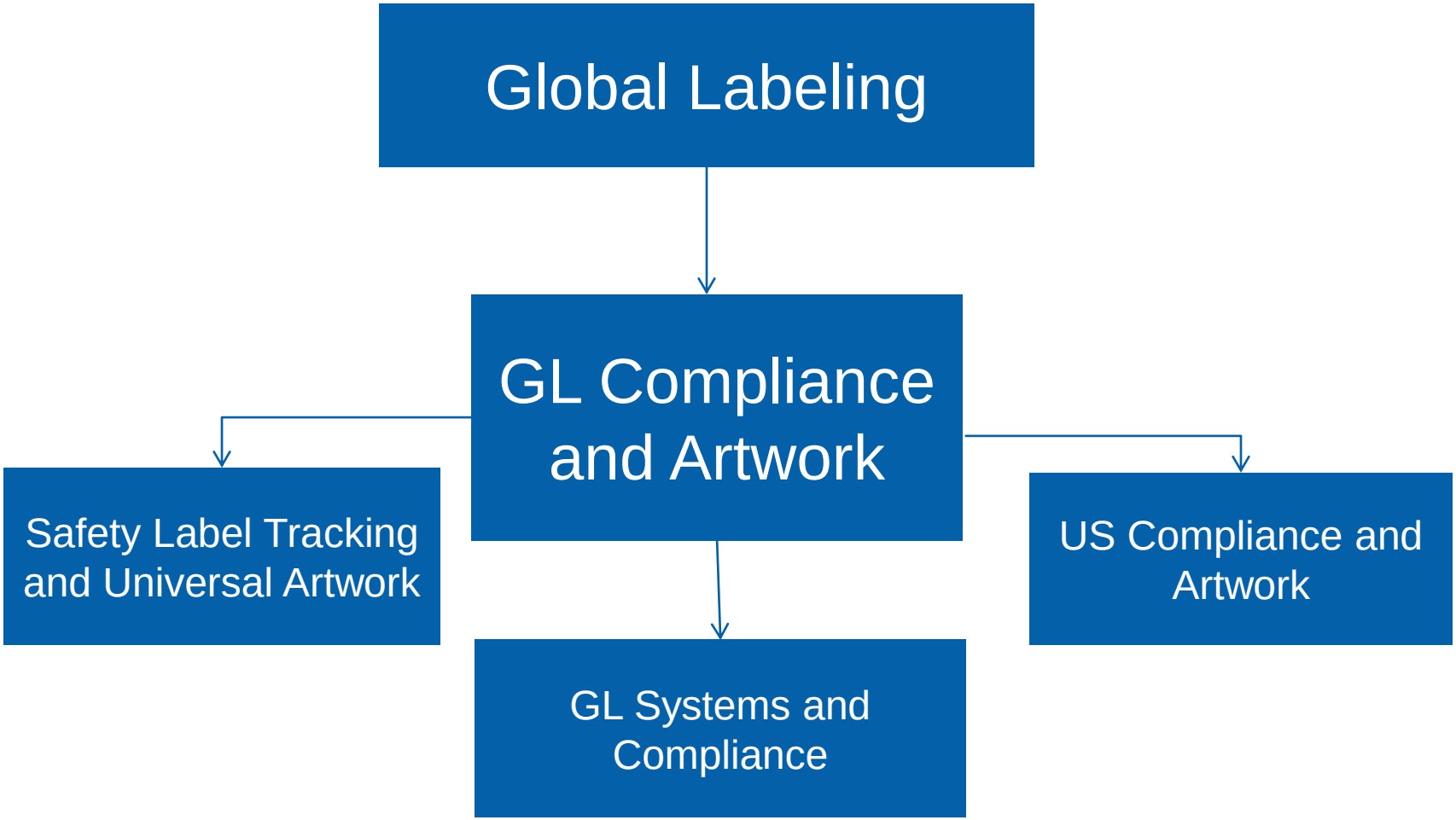
“The views and opinions expressed in the following PowerPoint and accompanying oral presentation should not be construed as official or unofficial FDA position.”

“The views expressed here are those of the author and do not necessarily represent or reflect the views of Novartis.”

Agenda

1. Overview of Global Labeling
2. SPL at Novartis
3. Systems and Tools
4. Managing New SPL Requirements
5. Challenges

Novartis Global Labeling



Governing Regulations

21CFR207

Title 21 → Chapter I → Subchapter C → Part 207

Browse Previous | Browse Next

Title 21: Food and Drugs

PART 207—REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS, AND THE NATIONAL DRUG CODE

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AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 371, 374, 381, 393; 42 U.S.C. 262, 264, 271.

SPL at Novartis

SPL is required for:

- Original NDA/BLA, Initial PAS, CBE
- Upon approval (or CBE/Annual Report)
- Change in Establishment Information / How Supplied

NOVARTIS → FDA U.S. FOOD & DRUG ADMINISTRATION → DAILYMED

SPL Components

- Content of Labeling – USPI (RA Responsible)
- Product Data Elements – Novartis Regulatory Information Management System/ RA CMC
- Principal Display Panel – US Artwork
- NDC – GL Systems and Compliance

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0078-0620-51	28 in 1 CARTON	07/29/2011	
1	NDC:0078-0620-61	1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Inactive Ingredients

Ingredient Name
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
MAGNESIUM STEARATE (UNII: 70097M6I30)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
HYPROMELLOSES (UNII: 3NXW29V3WO)
CROSPOVIDONE (UNII: 68401960MK)
MANNITOL (UNII: 3OWL53L36A)
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Differentiate Product Attributes for Accurate NDC Assignment

NDC Request Form

[redacted]

NDC/GDN Request

Date: 8-Dec-16
NDC Manager: Corey Schmidt
US LD: [redacted]
CMC Associate:
DRA Associate:

[redacted]

Kisqali (ribociclib)

Strength	Dosage Form	Package Type	Quantity	er Compone nt	If existing product are there changes as per 21CFR207.35(4)(1)?	Trade/Sampl	Controlled? Y	Country	NDC/GDN Assigned
200 mg daily dose (one 200 mg tablets)	TABLET, FILM COATED	ISTER PACK	21	Inner	N/A - New product	Trade	N	USA	0078-0860-01
200 mg daily dose (one 200 mg tablets)		RTON	1 x 21 (200mg)	Outer	N/A - New product	Trade	N	USA	0078-0860-01
400 mg daily dose (two 200 mg tablets)		ISTER PACK	14	Inner	N/A - New product	Trade	N	USA	0078-0867-14
400 mg daily dose (two 200 mg tablets)		RTON	3 x 14 (200mg)	Outer	N/A - New product	Trade	N	USA	0078-0867-42
600 mg daily dose (three 200 mg tablets)	TABLET, FILM COATED	BLISTER PACK	21	Inner	N/A - New product	Trade	N	USA	0078-0874-21
600 mg daily dose (three 200 mg tablets)	TABLET, FILM COATED	CARTON	3 x 21 (200mg)	Outer	N/A - New product	Trade	N	USA	0078-0874-63
600 mg daily dose									

TABLET, FILM COATED
TABLET, FILM COATED, EXTENDED RELEASE
TABLET, FOR SOLUTION
TABLET, FOR SUSPENSION
TABLET, MULTILAYER
TABLET, MULTILAYER, EXTENDED RELEASE
TABLET, ORALLY DISINTEGRATING
TABLET, ORALLY DISINTEGRATING, DELAYED

BLISTER PACK
BOTTLE
BOTTLE, DISPENSING
BOTTLE, DROPPER
BOTTLE, GLASS
BOTTLE, PLASTIC
BOTTLE, PUMP
BOTTLE, SPRAY

NOVARTIS

SPL at Novartis – FDA SPL View

AFINITOR- everolimus tablet
AFINITOR DISPERZ- everolimus tablet, for suspension
Novartis Pharmaceuticals Corporation

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AFINITOR safely and effectively. See full prescribing information for AFINITOR.

AFINITOR® (everolimus) tablets for oral administration
AFINITOR® DISPERZ (everolimus tablets for oral suspension)
Initial U.S. Approval: 2009

RECENT MAJOR CHANGES

Dosage and Administration (2.2, 2.5)	9/2017
Warnings and Precautions, Stomatitis (5.4)	9/2017
Warnings and Precautions, Embryo-Fetal Toxicity (5.12)	2/2016

INDICATIONS AND USAGE

AFINITOR is a kinase inhibitor indicated for the treatment of:

- Postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole. (1.1)
- Adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors. (1.2)
- Adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. (1.3)
- Adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. (1.4)

AFINITOR and AFINITOR DISPERZ are kinase inhibitors indicated for the treatment of:

- Pediatric and adult patients with tuberous sclerosis complex (TSC) who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. (1.5)

DOSAGE AND ADMINISTRATION

DOSAGE FORMS AND STRENGTHS

AFINITOR Tablets: 2.5 mg, 5 mg, 7.5 mg, and 10 mg tablets (3.1)
AFINITOR DISPERZ Tablets, for oral suspension: 2 mg, 3 mg, and 5 mg tablets (3.2)

CONTRAINDICATIONS

Hypersensitivity to everolimus, to other rapamycin derivatives, or to any of the excipients (4)

WARNINGS AND PRECAUTIONS

- Non-infectious pneumonitis: Monitor for clinical symptoms or radiological changes; fatal cases have occurred. Manage by dose reduction or discontinuation until symptoms resolve, and consider use of corticosteroids. (5.1)
- Infections: Increased risk of infections, some fatal. Monitor for signs and symptoms, and treat promptly. (5.2)
- Angioedema: Patients taking concomitant ACE inhibitor therapy may be at increased risk for angioedema. (5.3)
- Stomatitis: Stomatitis, including mouth ulcers and oral mucositis, occurs in most patients treated with AFINITOR. Initiation of topical treatment with dexamethasone mouthwash when starting AFINITOR reduces the incidence and severity of stomatitis. (5.4, 6.1)
- Renal failure: Cases of renal failure (including acute renal failure), some with a fatal outcome, have been observed. (5.5)
- Impaired wound healing: Increased risk of wound-related complications. Monitor signs and symptoms. Exercise caution in the peri-surgical period. (5.6)
- Laboratory test alterations: Elevations of serum creatinine, urinary protein, blood glucose, and lipids may occur. Decreases in hemoglobin, neutrophils, and platelets may also occur. Monitor renal function, blood glucose, lipids, and hematologic parameters prior to treatment and periodically thereafter. (5.8)
- Vaccinations: Avoid live vaccines and close contact with those who have received live vaccines. (5.11)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.12, 8.1, 8.3)

ADVERSE REACTIONS

Advanced HR+ BC, advanced NET, advanced RCC: Most common adverse reactions (incidence ≥30%) include stomatitis, infections, rash, fatigue, diarrhea, edema,

SPL at Novartis - DailyMed

DAILYMED

ALL DRUGS | HUMAN DRUGS | ANIMAL DRUGS | MORE WAYS TO SEARCH

Enter drug, NDC code, drug class, or Set ID

HOME | + NEWS | FDA GUIDANCES & INFO | + NLM SPL RESOURCES | + APPLICATION DEVELOPMENT SUPPORT | HELP

LABEL: AFINITOR- everolimus tablet
AFINITOR DISPERZ- everolimus tablet, for suspension

LABEL RSS SHARE

VIEW PACKAGE PHOTOS

VIEW MORE

SAFETY
- Report Adverse Events
- FDA Safety Recalls
- Presence in Breast Milk

RELATED RESOURCES
- Medline Plus
- Clinical Trials

NDC Code(s): 0078-0566-51, 0078-0566-61, 0078-0567-51, 0078-0567-61, view more
Packager: Novartis Pharmaceuticals Corporation

Category: HUMAN PRESCRIPTION DRUG LABEL
DEA Schedule: None
Marketing Status: New Drug Application

DRUG LABEL INFORMATION — Updated September 26, 2017

If you are a consumer or patient please visit this version.

DOWNLOAD DRUG LABEL INFO: PDF | XML — OFFICIAL LABEL (PRINTER FRIENDLY)

VIEW ALL SECTIONS

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AFINITOR safely and effectively. See full prescribing information for AFINITOR. AFINITOR® (everolimus) tablets ...

FULL PRESCRIBING INFORMATION: CONTENTS*

Table of Contents

FDA SPL Implementation Guide with Validation Procedures

Structured Product Labeling (SPL) Implementation Guide with Validation Procedures

Technical Specifications Document

This Document is incorporated by reference into the following Guidance Document(s):

Guidance for Industry – Electronic Submission of Lot Distribution Reports
Guidance to industry - Providing Regulatory Submissions in Electronic Format – Content of Labeling
Guidance for Industry - Providing Regulatory Submissions in Electronic Format – Drug Establishment Registration and Drug Listing
Guidance for Industry - SPL Standard for Content of Labeling Technical Questions and Answers
Guidance for Industry - Indexing Structured Product Labeling (Final)
Guidance for Industry: Self-Identification of Generic Drug Facilities, Sites, and Organizations
Guidance for Industry - Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry - Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act
Guidance for Industry - DSCSA Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics
Guidance for Industry - Compounding Animal Drugs from Bulk Drug Substances
Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling
Guidance for Industry - Format and Content of a REMS Document

For questions regarding this technical specifications document, contact spl@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)
Center for Veterinary Medicine (CVM)
October 2017

SPL File Conversion I

Source file – MS WORD

5.4 → ~~Oral Ulceration~~ Stomatitis¶

~~Mouth~~Stomatitis, including mouth ulcers~~, stomatitis,~~ and oral mucositis ~~have~~, has occurred in patients treated with AFINITOR at an incidence ranging from 44%-78% across the clinical trial experience. Grade 3 or 4 stomatitis was reported in 4%-9% of patients *[see Adverse Reactions (6.1, 6.2, 6.3, 6.4, 6.5)]*. ~~In such cases,~~ Stomatitis most often occurs within the first 8 weeks of treatment. When starting AFINITOR, initiating dexamethasone alcohol-free oral solution as a swish and spit mouthwash reduces the incidence and severity of stomatitis *[see Adverse Reactions (6.1) and Use in Specific Populations (8.4)]*. If stomatitis does occur, mouthwashes and/or other topical treatments are recommended, but alcohol-, hydrogen peroxide-, iodine-, or thyme- containing ~~mouthwashes~~ products should be avoided as they may exacerbate the condition ~~.~~ *[see Dosage and Administration (2.2)]*. Antifungal agents should not be used unless fungal infection has been diagnosed *[see Drug Interactions (7.1)]*.¶

5.5 → Renal Failure¶

Cases of renal failure (including acute renal failure), some with a fatal outcome, have been observed in patients treated

XML view


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SPL view

5.4 Stomatitis

Stomatitis, including mouth ulcers and oral mucositis, has occurred in patients treated with AFINITOR at an incidence ranging from 44%-78% across the clinical trial experience. Grade 3 or 4 stomatitis was reported in 4%-9% of patients *[see Adverse Reactions (6.1, 6.2, 6.3, 6.4, 6.5)]*. Stomatitis most often occurs within the first 8 weeks of treatment. When starting AFINITOR, initiating dexamethasone alcohol-free oral solution as a swish and spit mouthwash reduces the incidence and severity of stomatitis *[see Adverse Reactions (6.1) and Use in Specific Populations (8.4)]*. If stomatitis does occur, mouthwashes and/or other topical treatments are recommended, but alcohol-, hydrogen peroxide-, iodine-, or thyme-containing products should be avoided as they may exacerbate the condition *[see Dosage and Administration (2.2)]*. Antifungal agents should not be used unless fungal infection has been diagnosed *[see Drug Interactions (7.1)]*.

SPL File Conversion II

Source file – MS WORD

Table 1: AFINITOR Dose Adjustment and Management Recommendation for Adverse Reactions

Adverse Reaction	Severity[a]	AFINITOR Dose Adjustment[b] and Management Recommendations
Non-infectious pneumonitis	Grade 1 Asymptomatic, ~~radiographic findings~~clinical or diagnostic observations only; intervention not indicated	No dose adjustment required. Initiate appropriate monitoring.

XML view

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```

SPL view

Table 1: AFINITOR Dose Adjustment and Management Recommendation for Adverse Reactions

Adverse Reaction	Severity[a]	AFINITOR Dose Adjustment[b] and Management Recommendations
Non-infectious pneumonitis	Grade 1 Asymptomatic, clinical or diagnostic observations only; intervention not indicated	No dose adjustment required. Initiate appropriate monitoring.
	Grade 2 Symptomatic, medical intervention indicated; limiting instrumental ADL[c]	Consider interruption of therapy, rule out infection and consider treatment with corticosteroids until symptoms improve to Grade ≤ 1. Re-initiate treatment at a lower dose. Discontinue treatment if failure to recover within 4 weeks.
	Grade 3 Severe symptoms; limiting self-care ADL[c]; O_2 indicated	Interrupt treatment until symptoms resolve to Grade ≤1. Rule out infection and consider treatment with corticosteroids. Consider re-initiating treatment at a lower dose. If

SPL File Conversion – Product Data Elements

AFINITOR
everolimus tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0078-0566
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EVEROLIMUS (UNII: 9HW64Q8G6G) (EVEROLIMUS - UNII:9HW64Q8G6G)	EVEROLIMUS	5 mg


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NOVARTIS

SPL File Conversion – Inactive Ingredients

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Inactive Ingredients

Ingredient Name
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CROSPOVIDONE (UNII: 68401960MK)
HYPROMELLOSES (UNII: 3NXW29V3WO)
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)

SPL File Conversion – Establishment Information

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U.S. FOOD & DRUG ADMINISTRATION

Drug Establishments Current Registration Site

CSV Excel Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address
Novartis Pharma Stein AG	3002653483	488152505	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK;	Schaffhauserstrasse, Stein, CH-4332, Switzerland (CHE)

Establishment

Name	Address	ID/FEI	Business Operations
Novartis Pharma Stein AG		488152505	MANUFACTURE(0078-0566, 0078-0567, 0078-0594, 0078-0620, 0078-0626, 0078-0627, 0078-0628) , ANALYSIS(0078-0566, 0078-0567, 0078-0594, 0078-0620, 0078-0626, 0078-0627, 0078-0628) , PARTICLE SIZE REDUCTION(0078-0566, 0078-0567, 0078-0594, 0078-0620, 0078-0626, 0078-0627, 0078-0628)

Source File: Post-Approval Procedure

- SPL
- Novartis Website
- Global Repository
- Document Management System
- Promotional PI
- Artwork/Typeset

Closing the Loop

FPL Link File:

- File provided by Labeling to RA Associate
- Alerts FDA PM that the eListing requirement is complete

Novartis	Confidential	Page 1
NDA021588		Product Name: Gleevec
Module 1-14-2-2 Final package insert		

We have submitted the SPL file with drug listing; it can be found at the following location:

https://www.accessdata.fda.gov/spl/data/5552a1e8-7bbe-4829-88bd-e85b3b462094/5552a1e8-7bbe-4829-88bd-e85b3b462094.xml

NOVARTIS

Systems and Tools

- Global Labeling Repository
- Safety Label Tracking System
- NDC Database
- Document Management System
- QC Tools
- Comparison Tools
- Conversion Tools
- Regulatory Information Management (RIM) System

Managing New SPL Requirements

- Lot Distribution Data SPL
- REMS SPL
- No Change Certification SPL

Lot Distribution Data SPL

Novartis	Confidential	Page 1						[redacted]
Annual Report for BLA [redacted]		Product Name: [redacted]						
Period: 14th March 2017 - 13th Sept. 2017								
Distribution Data								

Trade Name, Dosage Form, and Strength	NDC Number	Bulk Lot No.	Fill Lot No.	Label Lot No.	Expiration Date	Distribution Date	No. of Doses Distributed	No. of Doses Returned / Reason
[redacted]	[redacted]	64338	64338	64338A	30.09.2018	03.04.2017 - 08.06.2017	63,510	0
[redacted]	[redacted]	64389	64389	64389A	31.10.2018	08.06.2017 - 13.09.2017	70,395	0
Total							133,905	0

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC-[redacted]	3 mL in 1 VIAL, SINGLE-USE		

Lot Distribution Data

Fill Lot Number	Bulk Lot Number	Substance					Quantity	Unit	DUNS
64338	64338	[redacted]							[redacted]
Final Container Lot Number	**NDC Package Code**	**Container Quantity (Doses)**	**Container Form**	**Distributed Containers (Doses)**	**Distribution Type**	**Initial Date**	**Expiration Date**	**Returned Containers (Doses)**	**DUNS**
64338A	[redacted]	3 mL (1)	VIAL, SINGLE-USE	63510 (63510)	Distributed per reporting interval	20170403	20180930	0 (0)	
Fill Lot Number	**Bulk Lot Number**	**Substance**					**Quantity**	**Unit**	**DUNS**
64389	64389	[redacted]							[redacted]
Final Container Lot Number	**NDC Package Code**	**Container Quantity (Doses)**	**Container Form**	**Distributed Containers (Doses)**	**Distribution Type**	**Initial Date**	**Expiration Date**	**Returned Containers (Doses)**	**DUNS**
64389A	[redacted]	3 mL (1)	VIAL, SINGLE-USE	70395 (70395)	Distributed per reporting interval	20170608	20181031	0 (0)	

Challenges

- Timelines: “as soon as possible but no later than 14 days”
- CBE Submissions
- Harnessing SPL Data
- XML (Structured) Authoring
- Integrations

Summary

1. Overview of Global Labeling
2. SPL at Novartis
3. Systems and Tools
4. Managing New SPL Requirements
5. Challenges

Thank you

NOVARTIS