CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208232Orig1s000

PRODUCT QUALITY REVIEW(S)

Recommendation:
Complete Response
(including the Overall Manufacturing Inspection Recommendation)

NDA 208232
Review #2
Review Date (see page 2)

Drug Name/Dosage Form	Octreotide delayed release capsule
Strength	20 mg
Route of Administration	oral
Rx/OTC Dispensed	Rx
Applicant	Chiasma Inc.
US agent, if applicable	n/a

SUBMISSION(S) REVIEWED	DOCUMENT DATE
0000	6/15/2015
0005	9/18/2015
0008	11/9/2015
0012	12/31/2015
0017	2/29/2016

Quality Review Team

DISCIPLINE	REVIEWER	DIVISION/OFFICE
Application Technical Lead	Suong Tran	New Drug Products I/ONDP
Regulatory Business Process Manager	Anika Lalmansingh	Regulatory Business Process Management I/OPRO
Drug Substance	Joseph Leginus	New Drug API/ONDP
Drug Product	Muthukumar Ramaswamy	New Drug Products II/ONDP
Biopharmaceutics	Vidula Kolhatkar	Biopharmaceutics/ONDP
Process	Pei-I Chu	Process Assessment II/OPF
Microbiology	Pei-I Chu	Process Assessment II/OPF
Facility	Tony Wilson	Inspectional Assessment/OPF

Executive Summary

I. Recommendation

The recommendation from the Office of Pharmaceutical Quality (OPQ) is for Complete Response.

- This recommendation replaces the 03/07/2016 recommendation that was finalized to meet the GRMP goal but the Overall Manufacturing Inspection Recommendation was still pending on that date.
- The Overall Manufacturing Inspection Recommendation for "Withhold" was finalized in Panorama on 04/08/2016. The Facilities review was finalized on 04/12/2016 (attached).
- There is no deficiency identified by the other review members of the OPQ team (see the 03/07/2016 review).

A. Recommendation and Conclusion on Approvability

1. Summary of Complete Response issues:

On 03/28/2016, FDA's Office of Regulatory Affairs informed CDER that the drug substance manufacturer (b) (4) FEI (b) (4) DMF (b) (4) located at (b) (4) currently has a pending Warning Letter. Subsequently, CDER OPQ/OPF issued a Overall Manufacturing Inspection Recommendationfor "Withhold" on 04/08/2016 and their review was finalized on 04/12/2016 (attached).

2. Action letter language:

"During a recent inspection of (b) (4) FEI (b) (4) located at (b) (4), our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved."

II. Summary of Quality Assessment

See the OPQ Integrated Quality Assessment/Review #1 finalized on 03/07/2016.

OVERALL ASSESSMENT AND SIGNATURE: EXECUTIVE SUMMARY

Application Technical Lead Signature:
I concur with the reviewers' conclusions.

Suong (Su) Tran, PhD, Quality/CMC Lead, OPQ

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/s/

JENNIFER L JOHNSON
08/14/2020 12:25:12 AM

Recommendation: Recommended for approval

NDA 208232
MYCAPSSA™ (OCTREOTIDE) DELAYED RELEASE CAPSULES
Review #2

Drug Name/Dosage Form	Delayed release capsules
Strength	20 mg
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	Chiasma Inc.
US agent, if applicable	None

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED
Resubmission	12/26/2019, 3/12/2020, and 5/18/2020	Drug product, Labeling

Quality Review Team

DISCIPLINE	Primary REVIEWER	BRANCH/DIVISION
Drug Substance	Joesph Leginus	ONDP New Drug API /Branch 1
Drug Product	Muthukumar Ramaswamy	ONDP/New Drug Products III/ Branch V /
Process/Facility	Peter Krommenhoek	OPMA Branch
Biopharamceutics	Rajesh Savkar	ONDP/Biopharmaceutics/ONDP
Regulatory Business Process Manager	Leeza Rahimi	OPRO
Application Technical Lead	Muthukumar Ramaswamy	ONDP/ New Drug Products III/ Branch V /ONDP

Quality Review Data Sheet

1. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	Type II		(b) (4)	Adequate	2/27/2020	LOA d6/17/2009
	Type III			Adequate	02/16/16	Based on information provided in the NDA

B. Other Documents: *IND, RLD, or sister applications*

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	108163	Octreotide acetate delayed release capsules

2. CONSULTS:

DISCIPLINE	STATUS	RECOMMENDATION	DATE	REVIEWER
Pharmacology/Toxicology	Complete	Adequate	2/17/16	Jessica Hawes (1st cycle review)

Executive Summary

I. **Recommendations:** The recommendation from the Office of Pharmaceutical Quality (OPQ) for NDA 208232 is approval. This recommendation includes acceptable recommendation for the facilities listed in the application.

A. Recommendation and Conclusion on Approvability

Mycapssa is a delayed release capsule containing octreotide acetate. Sandostain (octreotide acetate) injection was previously approved for treating acromegaly (NDA 19-667, Sandostatin injection). This is a 505(b)(2) application for a new dosage form of octreotide, that relies on FDA's previous findings of safety and efficacy for Sandostain injection as well as the applicant's comparative bioavailability and Phase 3 clincial studies. Primary benefit of the proposed oral dosage form is to avoid daily injections and to improve patient convenience. MYCAPSSA, 20 mg is intended for twice daily oral use (maximum dose/day: 80 mg; 4 capsules per day).

MYCAPSSA contains 20 mg of octreotide provided as (b) (4) an enteric coated size 0 hard gelatin capsule. MYCAPSSA also contains sodium caprylate, (b) (4) PVP -12 (b) (4), polysorbate 80, glycerol monocaprylate, glycerol tricaprylate, magnesium chloride and (b) (4). The enteric coating of the capsule avoids the release of active in the stomach. The MYCAPSSA capsules are packaged in blister packs and provided as Dosepak wallets (28 capsules/wallet).

This NDA 208232 received complete response on 4/15/2016 due to issues associated with drug substance manufacturing facility, (b) (4) (DMF # (b) (4) FEI (b) (4) and clincial deficiencies. There were no approvability issues with drug substance, drug product, process, and biopharmaceutics sections. On 12/29/2019, the applicant resubmitted the NDA. with updated drug substance facility information along with minor CMC updates to the drug substance and drug product sections.

OPQ CMC review team's recommendation for this NDA resubmission is approval. A shelf-life of 36 months is granted for MYCAPSSA capsules, when stored in Dosepak wallets at 2° to 8°C (36° to 46°F). The dose pack wallets should not be frozen. After first use, the opened wallets may be stored at 20° to 25°C (68° to 77°F) for up to 1 month.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable: None

II. Summary of Quality Assessments

A. Drug Substance Quality Summary

In this NDA resubmission, the applicant withdrew [redacted] as drug substance manufacturer from the NDA, and listed [redacted] as the only drug substance manufacturer (FEI [redacted]). The applicant referenced CMC information for octreotide acetate drug substance to [redacted] Type II DMF [redacted] Octreotide content of drug substance is calculated based on [redacted]. Dr. Joseph Leginus reviewed the drug substance information in the NDA and DMF [redacted] and concluded that the CMC information provided for drug substance is adequate to support the approval of this NDA. For additional information, please refer to Dr. Leginus's review in Panorama dated 4/2/2020.

B. Drug Product Quality Summary

MYCAPSSA delayed release capsule for oral administration is a white capsule printed with "OT 20" on one side in black ink. Each MYCAPSSA capsule contains 20 mg of octreotide (present as octretide acetate). The octreotide capsules are packaged in [redacted] blister strips with aluminum lidding and provided as Dosepak wallet (28 capsules).

The resubmission contains minor updates to drug product section (i.e., incoming tests for Opacode and Acryl-EZE, batch analysis information for drug product batches manufactured since the original submission, updated information on reference standard, and environmental assessment). There are no changes to the drug product composition, manufacturing process, drug product specification, dissolution method or dissolution acceptance criteria and stability information. Drug product reviewer Dr. Ramaswamy reviewed the information and concluded that it is adequate to support the NDA. Please refer to Dr. Ramaswamy's review in Panorama dated 5/18/2020.

Facilities associated with the application was reviewed by Dr. Peter Krommenhoek. The overall recommendation for the facilities with the application in Panorama is approve. Please refer to Dr. Krommenohoek's review in Panorama dated 5/18/2020.

The proposed dissolution acceptance criteria (Q = [redacted]% at 45 minutes) is supported by the available data. The applicant has committed to collect additional dissolution profile data including additional sampling time at [redacted] minutes on all commercial batches for one-year post approval and evaluate whether adoption of the Q = [redacted]% in [redacted] minutes specification rather than 45 minutes is practical. Please refer to Dr. Savkur's review in Panorama dated 5/7/2020.

Expiration Date & Storage Conditions remains the same: 36 months at 2° to 8°C (36° to 46°F) ("Keep refrigerated, do not freeze"). After first use: up to one (1) month at room temperature.

C. Summary of Drug Product Intended Use

Proprietary Name of the Drug Product	MYCAPSSA™ (octreotide) delayed release capsules
Non Proprietary Name of the Drug Product	Octereotide delayed release capsules
Non-Proprietary Name of the Drug Substance	Octreotide acetate
Proposed Indication(s) including Intended Patient Population	Acrmegaly
Duration of Treatment	Long-term
Maximum Daily Dose	80mg; 4 capsules per day
Alternative Methods of Administration	NA

OVERALL ASSESSMENT AND SIGNATURES:

OPQ recommendation for NDA 208232 is approval. This recommendation includes acceptable recommendation for the facilities listed in the application.

Application Technical Lead Signature:

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BIOPHARMACEUTICS

Product Background:
NDA/ANDA: NDA-208232-ORIG-1-RESUBMISSION-43

Drug Product Name / Strength: MYCAPSSA® (Octreotide delayed-release capsules)/20 mg

Route of Administration: Oral

Applicant Name: Chiasma Inc.

Review Summary:
The Applicant is developing a 20 mg delayed release capsule as an oral drug that is indicated for the treatment of acromegaly. The Applicant originally submitted this NDA (NDA-208232) under section 505(b)(2) on 6/15/2015. The listed drug (LD) product — Sandostatin® (Octreotide injection SC) — was approved under NDA 019667 on 10/21/1988. Octreotide, the drug substance, is a synthetic cyclic octapeptide analog of human somatostatin. The acetate salt of the drug substance that was selected for the development of Octreotide capsules was same as the LD product. The drug substance being a peptide, exhibits limited intestinal absorption due to low intestinal permeability and intraluminal enzymatic degradation. Furthermore, oral delivery of intact and biologically active peptides requires protection of the peptide (the drug substance) during the passage of the drug product through the acidic environment of the stomach and ready availability of the drug substance for absorption through the intestinal mucosa. To overcome these challenges, the Applicant developed a formulation to enable the oral delivery of peptides using a technology named Transient Permeability Enhancer (TPE®), which consists of (b) (4) (b) (4) (b) (4) TPE® is designed to protect the peptide drug from inactivation during the passage of the oral enteric coated dosage form through the gastrointestinal environment and subsequently, after the oral dosage form disintegrates in the intestines, to facilitate transfer of the intact and active peptide across the intestinal wall and into systemic circulation. The oral Octreotide product is expected to provide significant improvements with reduced symptoms and absence of injection site reactions.

The Biopharmaceutics assessment of the Original Submission concluded adequate. However, the Original Submission was issued a Complete Response Letter (dated 4/15/2016) due to deficiencies from other disciplines (see Link to deficiencies in CR Letter (see page 2)).

This Resubmission (RESUBMISSION-43; Sequence 0031) was submitted on 12/26/2019 in response to the CR letter dated 4/15/2016. From a Biopharmaceutics perspective, there is no new information/data that has been submitted by the Applicant in this Resubmission. Hence, the Biopharmaceutics assessment of the Original Submission stands valid and is appended in the *Biopharmaceutics Assessment* section of this Review. A summary of the assessment is presented below:

As part of the routine quality control, the Applicant developed an in-house dissolution method. The details of the dissolution method as agreed upon by the Agency and the Applicant are stated below:

Method:	In-house
Apparatus:	USP Apparatus II (paddle and sinker)
Medium/Volume:	Acid stage – 900 mL of 0.1 N HCl (pH 1.2) for 2 hours Buffer stage – 900 mL of pH 6.8 buffer for 45 minutes
Temperature:	37.0 ± 0.5 °C
Speed:	50 rpm

The Applicant proposed a dissolution acceptance criterion of:
Acid stage: At 2 hours, < (b)(4)% release (individual results)
Buffer stage: At 45 minutes, Q = (b)(4)% of the labeled amount (individual results)
The current dissolution acceptance criterion would be used for interim analysis for one year upon approval of the NDA. The Applicant would collect additional dissolution profile data including an additional time point of (b)(4) minutes on all commercial batches for one-year post approval. The newly generated dissolution profile data would be submitted for review to the Agency in the first annual report. Upon further review of the above dissolution profile data, the dissolution acceptance criterion will be further determined and finalized for implementation for release and stability testing of the drug product.

Being a delayed-release product, the Applicant evaluated the effects of alcohol dose-dumping in vitro. The results of the in vitro alcohol dose-dumping study revealed that low and moderate levels of alcohol (5% and 10% v/v ethanol) have no effect on the dissolution of the product, indicating that the delayed-release characteristics of the drug product are maintained. At alcohol concentrations >20% v/v, premature release of the drug is observed. As part of their justification, the Applicant stated that this would affect the efficacy rather than the safety of the drug product, and has requested a waiver of in vivo alcohol dose dumping study. The request for the waiver of in vivo alcohol dose dumping study would be evaluated/granted by the OCP Reviewer.

From a Biopharmaceutics perspective, this Reviewer concludes that NDA-208232-ORIG-1-RESUBMISSION-43 for Octreotide delayed-release capsules, 20 mg, is Adequate for approval.

Biopharmaceutics Assessment

The Biopharmaceutics assessment of the Original Submission is appended below:

NDA-208232-ORIG-1
BIOPHARMACEUTICS .

Rajesh Savkur

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Date: 5/05/2020 06:06:15PM
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Min Li

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Recommendation: NDA recommended for approval

NDA 208232
MYCAPSSA™ (OCTREOTIDE CAPSULES)
Review #1

Drug Name/Dosage Form	Delayed release capsules
Strength	20 mg (free peptide)
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	Chiasma Inc.
US agent, if applicable	None

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED
Original Amendment S001, S002, S005	6/15/2015 7/22/2015, 8/05/2015, 9/18/2015, 12/31/15	Drug product Drug Product

Quality Review Team

DISCIPLINE	REVIEWER	BRANCH/DIVISION
Drug Substance	Joe Leginus	ONDP /Drug substance
Drug Product	Muthukumar Ramaswamy	ONDP Branch VI /Drug Products
Process/Microbiology	Pei I Chu	OPF
Facility	Tony Wilson	OPF
Biopharmaceutics	Vidula Kolhatkar	ONDP/Biopharmaceutics
Regulatory Business Process Manager	Anika Lalman Singh	OPRO
Application Technical Lead	Su Tran	ONDP /Branch VI/Drug Products
Laboratory (OTR)	NA	
ORA Lead	NA	
Environmental Assessment (EA)	Muthukumar Ramaswamy	ONDP Branch VI /Drug Products

Table of Contents

Quality Review Data Sheet

1. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	Type III	(b) (4) (b) (4)	(b) (4) (b) (4) (b) (4) (b) (4)	Adequate	02/16/16	Based on information provided in the NDA
	Type I					

B. Other Documents: *IND, RLD, or sister applications*

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	108163	Octreotide acetate delayed release capsules

2. CONSULTS:

DISCIPLINE	STATUS	RECOMMENDATION	DATE	REVIEWER
Pharmacology/Toxicology	Complete	Adequate	2/17/16	Jessica Hawes

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The active moiety is part of an approved drug in the United states.
Chiasma has calculated the estimated concentration of the substance at the point of entry into the aquatic environment and the calculated values will be below 1 part per billion.

Chiasma's octreotide oral capsules will be available as an alternate drug to currently approved parenteral products, the new product would displace the use of marketed products. Hence the use of Chiasma' s product will not increase the use of the active moiety in the environment.

EIC-Aquatic (ppb) =Ax B x C x D where

(b) (4)

Chiasma states that it will adhere to all Federal, State and Local environmental laws.

Reviewer's Assessment: Adequate

Based on the above exemption justification, CMC reviewer recommends that a categorical exclusion from environmental assessment can be granted.

OVERALL ASSESSMENT AND SIGNATURES: ENVIRONMENTAL

Reviewer's Assessment and Signature:

Muthukumar Ramaswamy -S

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Date: 2016.02.26 11:19:15 -05'00'

Secondary Review Comments and Concurrence:
I concur with the reviewer's assessment.

Danae D. Christodoulou -S

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I. Review of Common Technical Document-Quality (Ctd-Q) Module 1

Labeling & Package Insert

For NDA only

1. **Package Insert**

(a) "Highlights" Section (21CFR 201.57(a))
(Attach proposed text)

Item	Information Provided in NDA	Reviewer's Assessment
Product title, Drug name (201.57(a)(2))		
Proprietary name and established name	MYCAPSSA Octreotide	Proprietary name MYCAPSSA is acceptable. Revise the drug name to (Octreotide) delayed release capsules
Dosage form, route of administration	Capsules, oral	Delayed release capsules
Controlled drug substance symbol (if applicable)	NA	
Dosage Forms and Strengths (201.57(a)(8))		
A concise summary of dosage forms and strengths	Enteric coated octreotide capsules containing 20 mg Octreotide (free base)	None

Conclusion: Adequate with comment
Revise the drug name to (Octreotide) delayed release capsules.

(b) "Full Prescribing Information" Section

 # 3: Dosage Forms and Strengths (21CFR 201.57(c)(4))

Item	Information Provided in NDA	Reviewer's Assessment
Available dosage forms	Enteric coated capsule	
Strengths: in metric system	20 mg	
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable.	none	Each capsule is printed with "OT 20" in Opacode® black ink

Conclusion: Include the following to Dosage Forms and Strength section
Each capsule is printed with "OT 20" in Opacode® black ink

#11: Description (21CFR 201.57(c)(12))

(b) (4)

(b) (4) Octreotide is known chemically as L-Cysteinamide, D-phenylalanyl-L-cysteinyl-L-phenylalanyl-D-tryptophyl-L-lysyl-L-threonyl-N-[2-hydroxy-1-(hydroxy-methyl) propyl]-, cyclic (2→7)-disulfide; [R-(R*,R*)].
The molecular weight of octreotide is 1019.3 (free peptide, C49H66N10O10S2) and its amino acid sequence is:

H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Thr-ol,
xCH_3COOH where x = 1.4 to 2.5

MYCAPSSA is provided as an enteric-coated capsule containing 20 mg of octreotide (20 mg calculated as free base), polyvinylpyrrolidone (PVP-12), sodium caprylate, magnesium chloride, polysorbate 80, glyceryl monocaprylate, glyceryl tricaprylate, gelatin, gelatin capsules and Acryl-EZE® (methacrylate). The capsule is printed with "OT 20" in Opacode® black ink.

MYCAPSSA is lactose-free and gluten-free.

Item	Information Provided in NDA	Reviewer's Assessment
Proprietary name and established name	MYCAPSSA Octreotide	Adequate
Dosage form and route of administration	Capsules, oral	Delayed release capsules
Active moiety expression of strength with equivalence statement for salt (if applicable)	20 mg (free base)	Adequate
Inactive ingredient information (quantitative, if injectable 21CFR201.100(b)(5)(iii)), listed by USP/NF names.	Polyvinylpyrrolidone (PVP-12), sodium caprylate, magnesium chloride, polysorbate 80, glyceryl monocaprylate, glyceryl tricaprylate, gelatin, gelatin capsules and Acryl-EZE® (methacrylate).	Adequate with comment. Remove the following statement from section (b) (4) (b) (4)
Statement of being sterile (if applicable)	Not applicable	
Pharmacological/ therapeutic class	Octreotide is an analog of human somatostatin.	Adequate
Chemical name, structural formula, molecular weight		
If radioactive, statement of important nuclear characteristics.	none	
Other important chemical or physical properties (such as pKa, solubility, or pH)	Provides a description of the drug chemical name, molecular weight, amino acid sequence, and the salt form.	Adequate

Conclusion: Adequate with comment
Remove the following statement from section (b) (4) (b) (4)

#16: How Supplied/Storage and Handling (21CFR 201.57(c)(17))

MYCAPSSA is supplied in wallets, each containing 28 capsules.

NDC Number	Package Size
XXXXX-XXX-XX	Wallet of 28 capsules

Storage: Until first use, store unopened wallets of MYCAPSSA at 36° to 46°F (2° to 8°C). KEEP REFRIGERATED. DO NOT FREEZE.

After first use, opened wallets may be stored at 68° to 77°F (20° to 25°C) for up to 1 month.

Item	Information Provided in NDA	Reviewer's Assessment
Strength of dosage form		Not described in Section 16
Available units (e.g., bottles of 100 tablets)	28 capsules/wallet	MYCAPSSA is packaged as 7 capsules per blister strip. Dose wallets contain 28 capsules (4 blister strips/dose wallet)
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	NDC Number	Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting not described
Special handling (e.g., protect from light, do not freeze)	Unopened wallets store at MYCAPSSA at 36° to 46°F (2° to 8°C). KEEP REFRIGERATED. Opened wallets store at 68° to 77°F (20° to 25°C) for up to 1 month	Adequate
Storage conditions	Do not freeze	Adequate

Manufacturer/distributor name listed at the end of PI, following Section #17

Item	Information Provided in NDA	Reviewer's Assessment
Manufacturer/distributor name (21 CFR 201.1)	Manufactured by Encap Drug Delivery, Scotland, UK.	Adequate

Conclusion: Adequate with comment

Include capsules imprinting information under section 16

2. Container and Carton Labeling

Octreotide capsules are packaged in blister strips (7 capsules/strip x 4 strips) are packaged in a (b) (4) (b) (4) cardboard medication card, which is then folded inside an outer card. The combination is called DosePak.

1) Immediate Container Label

Label for medication card:

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Item	Comments on the Information Provided in NDA	Conclusions
Proprietary name, established name (font size and prominence (21 CFR 201.10(g)(2))	Revise dosage form description from (b) (4) (b) (4); to octreotide delayed release capsules	
Strength (21CFR 201.10(d)(1); 21.CFR 201.100(b)(4))	20 mg	
Route of administration 21.CFR 201.100(b)(3))	Dose administration instruction specified	
Net contents* (21 CFR 201.51(a))	Yes	
Name of all inactive ingredients 21CFR 201.100(b)(5)**	No	Deficiency
Lot number per 21 CFR 201.18	Yes	
Expiration date per 21 CFR 201.17	Yes	
"Rx only" statement per 21 CFR 201.100(b)(1)	Yes	
Storage (not required)	Specified	
NDC number (per 21 CFR 201.2) (requested, but not required for all labels or labeling), also see 21 CFR 207.35(b)(3)	yes	
Bar Code per 21 CFR 201.25(c)(2)***	Yes	
Name of manufacturer/distributor (21 CFR 201.1)	Yes	
Others		

*21 CFR 201.51(h) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled ''sample'', ''physician's sample'', or a substantially similar statement and the contents of the package do not exceed 8 grams.
**For solid oral dosage forms, CDER policy provides for exclusion of "oral" from the container label
**Not required for Physician's samples..

Conclusion: Name of all inactive ingredients should be specified on the DosePak label.

OVERALL ASSESSMENT AND SIGNATURES: LABELING

Reviewer's Assessment and Signature:

Muthukumar Ramaswamy -S

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Date: 2016.02.26 11:20:04 -05'00'

Secondary Review Comments and Concurrence:
I concur with the reviewer's recommendations.

Danae D. Christodoulou -S

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II. List of Deficiencies To Be Communicated

Label/Labeling

4) Revise the drug name to (Octreotide) delayed release capsules throughout the label
5) Include capsules imprinting information under Section 16.
6) Remove the following statement from section (b) (4) (b) (4)