ANDA FILING CHECKLIST

(CTD or eCTD FORMAT)

FOR COMPLETENESS AND ACCEPTABILITY of an APPLICATION

ANDA:
APPLICANT:
RELATED APPLICATION(S):

DRUG NAME:
DOSAGE FORM:

LETTER DATE:
RECEIVED DATE:

☐ P-IV
☐ FIRST GENERIC
☐ EXPEDITED REVIEW REQUEST: MaPP 5240.1, MaPP 5240.3 or GDUFA (Approved/Denied)
☐ PEPFAR
☐ PET

Electronic or Paper Submission: SELECT Type II DMF#

BASIS OF SUBMISSION:
NDA/ANDA:
FIRM:
RLD:

****Document Room Note: for New Strength amendments and supplements, if specific reviewer(s) have already been assigned for the original, please assign to those reviewer(s) instead of the default random team(s).**

Review Team:

CHEM Team: ☐ **Activity**	Division of Bioequivalence: ☐ **Activity**
RPM: ☐ **FYI**	Division of Bioequivalence PM: ☐ **FYI**
CHEM PQRPM: ☐ **FYI**	Division of Clinical Review: **(No)** ☐ **Activity**
CHEM Team Leader: ☐ **No Assignment Needed in DARRTS**	DMF Review Team Leader: **Dave Skanchy** ☒ **FYI**
Dissolution Review: ☐ **FYI**	
Labeling Reviewer: ☐ **Activity**	Micro Review: **(No)** ☐ **Activity**
SPECIAL INSTRUCTIONS FOR DOCUMENT ROOM (applicable only for a response to a refuse to receive):	

Regulatory Reviewer: Date:	Recommendation: ☐ **FILE** ☐ **REFUSE to RECEIVE**

Comments:
Therapeutic Code:
On Cards:
Archival copy:

- **For More Information on Submission of an ANDA in Electronic Common Technical Document (eCTD) Format please go to:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm
- **For a Comprehensive Table of Contents Headings and Hierarchy please go to: http://www.fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf**
- **For more** CTD and eCTD informational links **see the final page of the ANDA Checklist**

1. Edit Application Property Type in DARRTS where applicable for

a. First Generic Received
☐ Yes ☐ No
b. Market Availability
☐ Rx ☐ OTC
c. PEPFAR
☐ Yes ☐ No
d. Product Type
☐ Small Molecule Drug
e. USP Drug Product (at time of filing review)
☐ Yes ☐ No

2. Edit Submission Patent Records in DAARTS
   ☐ Yes
3. Edit Contacts Database with Bioequivalence Recordation where applicable
   ☐ Yes
4. EER (internal notation: RSB to submit at time of filing)
   ☐ Yes
5. GDUFA Obligation Met (Filing Fee, Type II DMF Fee, and Facility Fee)
   ☐ Yes - (internal notation-if not met contact: cder-om-collection@fda.hhs.gov)
6. DMF Complete Assessment
   ☐ Yes

ADDITIONAL COMMENTS REGARDING THE ANDA:

MODULE 1: ADMINISTRATIVE

		COMMENT (S)
1.1	**1.1.2** **Signed and Completed Application Form (356h)** (Rx/OTC Status) Select (original signature) Refer to the links provided for the newly revised form 356h and updated instructions. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM321897.pdf http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/ucm082348.pdf **** PLACE ESTABLISHMENT CONTACT INFORMATION IN SECTION 29: MANUFACTURING STEPS AND/OR TYPE OF TESTING****	
1.2	**Cover Letter** Select **Is the drug product subject to REMS requirements?** ☐ Yes ☐ No Refer to the link below to determine if the product is a REMS product. **http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111350.htm** If the product is subject to REMS, send an email to Mary Dempsey informing her the ANDA has been submitted	
1.2.1	**Form FDA 3674 (PDF)** Select	
*	**Table of Contents** (paper submission only) Select	
1.3.1.2	**US Agent Appointment Letter** (U.S. Agent [if needed, countersignature on 356h]) Select (both applicant and Type II DMF holder, if applicable)	
1.3.2	**Field Copy Certification** 21CFR 314.94(d)(5) (original signature) Select	
1.3.3	**Debarment Certification-GDEA** (Generic Drug Enforcement Act)/Other: (no qualifying statement) 1. Debarment Certification (original signature) Select 2. List of Convictions statement (original signature) Select	
1.3.4	**Financial Certifications** Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) Select Disclosure Statement (Form FDA 3455) Select	
1.3.5	**Patent Information** Patents listed for the RLD in the Electronic Orange Book Approved Drug Products with Therapeutic Equivalence Evaluations **Patent Certification** [21 CFR 314.94 (a)(12)/505(j)(2)(A)(vii)] 1. Patent number(s) 2. Paragraph: (Check all certifications that apply) MOU ☐ PI ☐ PII ☐ PIII ☐ PIV ☐ Statement of Notification (21 CFR 314.95/505(j)(2)(B)) ☐ 3. Expiration of Patent(s): a. Pediatric exclusivity submitted? Select b. Expiration of Pediatric Exclusivity? 4. Exclusivity Statement: State marketing intentions?	
1.4.1	**References** Letters of Authorization 1. DMF letters of authorization a. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient Select b. Type II DMF# c. Type III DMF authorization letter(s) for container closure Select d. Type III or V DMF authorization letter(s) for sterile product sterilization process Select	
1.12.4	**Request for Comments and Advice** - Proprietary name requested Select If Yes, did the firm provide the request as a separate electronic amendment labeled	

	"Proprietary Name Request" at initial time of filing 1. Yes Select 2. No - contact the firm to submit the request as a separate electronic amendment.	
1.12.11	**Basis for Submission** NDA#: Ref Listed Drug: Firm: **ANDA suitability petition required?** Select If Yes, provide petition number and copy of approved petition **ANDA Citizen's Petition Required?** Select If Yes, provide petition number and copy of petition	
1.12.12	**Comparison between Generic Drug and RLD-505(j)(2)(A)** 1. Conditions of use Select 2. Active ingredients Select 3. Inactive ingredients Select 4. Route of administration Select 5. Dosage Form Select 6. Strength Select	
1.12.14	**Environmental Impact Analysis Statement** (cite 21CFR 25.31 and 25.15(d), if applicable) Select	
1.12.15	**Request for Waiver** (cite 21 CFR 320.22 or 320.24(b)(6)) Request for Waiver of In-Vivo BA/BE Study(ies) Select	
1.14.1	**Draft Labeling** (Multi Copies N/A for E-Submissions) **1.14.1.1** 4 copies of draft for paper submission only (each strength and container) Select **1.14.1.2** Side by side labeling comparison of container(s) and carton(s) for each strength with all differences visually highlighted and annotated **1.14.1.3** 1 package insert (content of labeling) in PDF and WORD format, and SPL submitted electronically **1.14.1.4** Labeling Comprehension Studies Refer to Pharmacy Bulk Package Sterility Assurance Table (for PBP's only) See link below for table: http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM352612.pdf	
	Listed Drug Labeling **1.14.3.1** 1 side by side labeling (package and patient insert) comparison with all differences visually highlighted and annotated Select **1.14.3.3** RLD package insert, 1 RLD container label, and if applicable, 1 RLD outer container label Select	

MODULE 2: Quality Overall Summary

		COMMENT (S)
2.3	**Quality Overall Summary (QOS)** **E-Submission: PDF** Select **Word Processed e.g., MS Word** Select **Additional information regarding QbR may be found at the following link:** http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120971.htm **Question based Review (QbR)** Select **2.3.S Drug Substance (Active Pharmaceutical Ingredient)** Select 2.3.S.1 General Information 2.3.S.2 Manufacture 2.3.S.3 Characterization 2.3.S.4 Control of Drug Substance 2.3.S.5 Reference Standards or Materials 2.3.S.6 Container Closure System 2.3.S.7 Stability **2.3.P Drug Product** Select 2.3.P.1 Description and Composition of the Drug Product 2.3.P.2 Pharmaceutical Development 2.3.P.2.1 Components of the Drug Product 2.3.P.2.1.1 Drug Substance 2.3.P.2.1.2 Excipients 2.3.P.2.2 Drug Product **Oral Solids**: Immediate Release or Modified Release (Matrix Technology or Compressed Film Coated Components) tablet scoring data per Draft *Guidance for Industry, Tablet Scoring: Nomenclature, Labeling and Data for Evaluation* (if applicable) 2.3.P.2.3 Manufacturing Process Development 2.3.P.2.4 Container Closure System 2.3.P.3 Manufacture 2.3.P.4 Control of Excipients 2.3.P.5 Control of Drug Product 2.3.P.6 Reference Standards or Materials 2.3.P.7 Container Closure System 2.3.P.8 Stability	

MODULE 2.7: Clinical Summary

		COMMENT (S)
2.7	**Clinical Summary (Bioequivalence)**Model BE Data Summary Tables **http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM120957.pdf** **** In addition to the standard tables, see the link above for tables specifically designed for in-vitro binding studies **** **http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM364105.pdf** **E-Submission: PDF** Select **Word Processed: e.g., MS Word** Select **2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods** **2.7.1.1 Background and Overview** Table 1. Submission Summary Select Table 4. Bioanalytical Method Validation Select Table 6. Formulation Data Select Table 10. Study Information Select Table 11. Product Information Select Table 17. Comparative Physiochemical Data of Ophthalmic Solution Products Select **2.7.1.2 Summary of Results of Individual Studies** Table 5. Summary of In Vitro Dissolution Select (include complete comparative In Vitro Dissolution Data (individual) with Certificate of Analysis [CoA] for Test and Reference products including: potency, assay, content uniformity, date of manufacture and lot number) Table 9. Reanalysis of Study Samples Select Table 12. Dropout Information Select Table 13. Protocol Deviation Select Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analysis Select **2.7.1.3 Comparison and Analyses of Results Across Studies** Table 2. Summary of Bioavailability (BA) Studies Select Table 3. Statistical Summary of the Comparative BA Data: 1. Unscaled Average – Table A 2. Reference-scaled Average BE Studies – Tables A **and** B BE Studies Select Table 16. Composition of Meal Used in Fed Bioequivalence Study Select **2.7.1.4 Appendix** Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples Select **2.7.4.1.3 Demographic and Other Characteristics of Study Population** Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study Select **2.7.4.2.1.1 Common Adverse Events** Table 8. Incidence of Adverse Events in Individual Studies Select	

MODULE 3: 3.2.S DRUG SUBSTANCE

<table>
<tr><td></td><td></td><td>COMMENT (S)</td></tr>
<tr><td>3.2.S.1</td><td>General Information) Select
(Do not refer to DMF)
3.2.S.1.1 Nomenclature
3.2.S.1.2 Structure
3.2.S.1.3 General Properties</td><td></td></tr>
<tr><td>3.2.S.2</td><td>Manufacturer
Drug Substance (Active Pharmaceutical Ingredient)
Must correlate to the establishment information submitted in annex to Form FDA 356h.
1. Name and Full Address(es)of the Facility(ies) Select
2. Contact name, phone and fax numbers, email address Select
3. U.S Agent's name (if applicable) Select
4. Specify Function or Responsibility Select
5. Type II DMF number for API
6. CFN, FEI or DUNS numbers (if available)</td><td></td></tr>
<tr><td>3.2.S.3</td><td>Characterization Select

Provide the following in tabular format as follows:

<table>
<tr><td>IUPAC Chemical Name</td><td>Code #</td><td>Chemical Structure</td><td>Process/ Degradation Impurity</td><td>Source/ Mechanism</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>

http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf</td><td></td></tr>
</table>

<table>
<tr>
<td>3.2.S.4</td>
<td>
Control of Drug Substance (Active Pharmaceutical Ingredient)
3.2.S.4.1 Specification
Testing specifications and data from drug substance manufacturer(s) Select
3.2.S.4.2 Analytical Procedures Select
3.2.S.4.3 Validation of Analytical Procedures
(API that is USP or reference made to DMF, must provide verification of USP or DMF procedures) Select
1. Spectra and chromatograms for reference standards and test samples Select
2. Samples-Statement of Availability and Identification of:
a. Drug Substance Select
b. API lot numbers
3.2.S.4.4 Batch Analysis
1. COAs specifications and test results from drug substance mfgr(s) Select
2. Drug Product manufacturer's Certificates of analysis Select
3.2.S.4.5 Justification of Specification Select

Provide data in tabular format:
<table>
<tr><th>Chemical Name</th><th>Code#</th><th>MDD</th><th>IT</th><th>QT</th><th>TDI of Impurity</th><th>Proposed AC for Unspecified Impurities</th><th>Proposed AC for Specified Impurities</th><th>Justification if AC>QT for Specified Impurities</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf
</td>
<td></td>
</tr>
<tr>
<td>3.2.S.5</td>
<td>Reference Standards or Materials (Do not refer to DMF) Select</td>
<td></td>
</tr>
<tr>
<td>3.2.S.6</td>
<td>Container Closure Systems Select</td>
<td></td>
</tr>
<tr>
<td>3.2.S.7</td>
<td>Stability
1. Retest date or expiration date of API Select</td>
<td></td>
</tr>
</table>

MODULE 3: 3.2.P DRUG PRODUCT

		COMMENT (S)
3.2.P.1	**Description and Composition of the Drug Product** 1. Unit composition with indication of the function of the inactive ingredient(s) Select 2. Inactive ingredients and amounts are appropriate per IIG (per/dose justification) (provide justification in a tabular format) Select 3. Conversion from % to mg/dose values for inactive ingredients (if applicable) Select 4. Elemental iron: provide daily elemental iron calculation or statement of adherence to 21CFR73.1200 (calculation of elemental iron intake based on **maximum daily dose (MDD)** of the drug product is preferred if this section is applicable) Select 5. Injections: If the reference listed drug is packaged with a drug specific diluent then the diluent must be Q1/Q2 and must be provided in the package configuration Select	
3.2.P.2	**Pharmaceutical Development** 1. Pharmaceutical Development Report Select 2. Microbial Attributes a. Container/Closure Integrity Testing Report for Sterile Products b. Antimicrobial Effectiveness Testing for Multi-dose sterile products	
3.2.P.3	**Manufacture** **3.2.P.3.1 Drug Product** Must correlate to the establishment information submitted in annex to From FDA 356h for the finished dosage manufacturer and all outside contract testing laboratories. 1. Name and Full Address(es)of the Facility(ies) Select 2. Contact name, phone and fax numbers, email address Select 3. U.S Agent's name (if applicable) Select 4. Specify Function or Responsibility Select 5 CGMP Certification (from both applicant and drug product manufacturer if different entities) Select 6. CFN, FEI or DUNS numbers (if available) **3.2.P.3.2 Batch Formula** Select **3.2.P.3.3 Description of Manufacturing Process and Process Controls** 1. Description of the Manufacturing Process and (for aseptic fill products) Facility Select 2. Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified Select 3. Master packaging records for intended marketing container(s) Select 4. If sterile product Select 5. Reprocessing Statement (cite 21CFR 211.115, submitted by the drug product manufacturer and the applicant, if different entities) Select **3.2.P.3.4 Controls of Critical Steps and Intermediates** Select **3.2.P.3.5 Process Validation and/or Evaluation** 1. Terminally Sterilized Product Select a. Validation of production terminal sterilization process b. Validation of depyrogenation of all product containers and closures c. Validation of container-closure package integrity 2. Aseptically Filled Product Select • Validation (bacterial retention studies) of sterilizing grade filter(s) • Validation of the sterilization of sterile bulk drug or product contact equipment, components, containers, and closures • Validation of depyrogenation of product containers and closures • Validation of aseptic filling process/line/room (media fills/process simulations) • Validation of container-closure package integrity	
3.2.P.4	**Controls of Excipients** (Inactive Ingredients) Source of inactive ingredients identified Select **3.2.P.4.1 Specifications** 1. Testing specifications (including identification and characterization) Select	

<table>
<tr><td></td><td>2. Suppliers' COA (specifications and test results) Select
3.2.P.4.2 Analytical Procedures Select
3.2.P.4.3 Validation of Analytical Procedures Select
3.2.P.4.4 Justification of Specifications:
1. Applicant COA Select</td><td></td></tr>
<tr><td>3.2.P.5</td><td>Controls of Drug Product
3.2.P.5.1 Specification(s) Select
3.2.P.5.2 Analytical Procedures Select
3.2.P.5.3 Validation of Analytical Procedures
(if using USP procedure, must provide verification of USP procedure) Select
Samples - Statement of Availability and Identification of:
1. Finished Dosage Form Select
2. Lot numbers and strength of Drug Products
3.2.P.5.4 Batch Analysis
Certificates of Analysis for Finished Dosage Form Select
3.2.P.5.5 Characterization of Impurities Select
Provide in tabular format as below:
<table>
<tr><th>IUPAC Chemical Name</th><th>Code #</th><th>Chemical Structure</th><th>Degradation Impurity</th><th>Source/ Mechanism</th></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table>
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf

3.2.P.5.6 Justification of Specifications Select</td><td></td></tr>
<tr><td>3.2.P.7</td><td>Container Closure System
1. Summary of Container/Closure System (if new resin, provide data) Select
2. Components Specification and Test Data Select
3. Packaging Configuration and Sizes
4. Container/Closure Testing (recommended additional testing for all plastic)Select
a. Solid Orals: water permeation, light transmissionSelect
b. Liquids: leachables, extractables, light transmissionSelect
5. Source of supply and suppliers address Select</td><td></td></tr>
<tr><td>3.2.P.8</td><td>3.2.P.8.1 Stability and Conclusions (Finished Dosage Form)
1. Stability Protocol submitted Select
2. Expiration Dating Period for Marketed Packaging
3. Expiration Dating Period for Bulk Packaging (if applicable)
3.2.P.8.2 Post-approval Stability Protocol and Stability Commitment
(From Applicant and Drug Product Manufacturer, if different entities)
Post Approval Stability Protocol and Commitments Select
3.2.P.8.3 Stability Data
1. Accelerated stability data
a. Four (4) time points 0,1,2,3 Select
-OR-
b. . Refer to the Final Guidance for Industry ANDAs: Stability Testing Drug Substances and Products, dated June 2013 Select

c. For liquid and semi-solid products, upright and inverted/horizontal storage orientation Select</td><td></td></tr>
</table>

	2. Batch numbers on stability records the same as the test batch Select 3. Date accelerated stability study initiated Select 4. Date accelerated stability sample(s) removed from stability chamber for each testing time point Select	

MODULE 3: 3.2.R REGIONAL INFORMATION (Drug Substance)

		COMMENT (S)
3.2.R Drug Substance	**3.2.R.1.S Executed Batch Records for drug substance (if available)** Select **3.2.R.2.S Comparability Protocols** Select **3.2.R.3.S Methods Validation Package** Select Methods Validation Package (3 copies for paper and N/A for E-Submissions) (Required for Non-USP drugs)	

MODULE 3: 3.2.R REGIONAL INFORMATION (Drug Product)

		COMMENT (S)
3.2.R Drug Product	**3.2.R.1.P.1** **Executed Batch Records** Copy of Executed Batch Record with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures) Batch Reconciliation and Label Reconciliation Select a. Theoretical Yield b. Actual Yield c. Packaged Yield Bulk Package Reconciliation for all bulk packaging considered a commercial container is required if bulk packaging is used to achieve the minimum package requirement. Provide the following information in their respective sections: a. Bulk Package Label (1.14.1) Select b. Bulk Package Stability (3.2.P.8) 1. If bulk is to be shipped, provide accelerated stability data at 0,3,6 months Select 2. If bulk is only warehoused for repackaging, provide RT stability data at 0,3,6 months Select c. Bulk Package Container and Closure information (3.2.P.7) Select **3.2.R.1.P.2 Information on Components** Select **3.2.R.2.P Comparability Protocols** Select **3.2.R.3.P Methods Validation Package** Select Methods Validation Package (3 copies for paper and N/A for E-Submissions) (Required for Non-USP drugs)	

MODULE 5: CLINICAL STUDY REPORTS

		COMMENT (S)
5.2	**Tabular Listing of Clinical Studies** Select	
5.3.1 (complete study data)	**Bioavailability/Bioequivalence** **1. Formulation data same?** a. Comparison of all Strengths (proportionality of multiple strengths) Select b. Parenterals, Ophthalmics, Otics and Topicals (21 CFR 314.94 (a)(9)(iii)-(v) **2. Lot Numbers and strength of Products used in BE Study(ies)** **3. Study Type: IN-VIVO PK STUDY(IES)** (Continue with the appropriate study type box below)	
	See Module 2.7 Clinical Summary for placement of BA/BE Summary for tables 9 – 16. **The study data that support the BA/BE summary tables should be provided in the corresponding sections below:** **5.3.1.2 Comparative BA/BE Study Reports** **5.3.1.3 In Vitro-In-Vivo Correlation Study Reports (exception: all dissolution data should be placed in 2.7)** **5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies** **Case Report Forms** should be placed under the study to which they pertain, and appropriately tagged. Refer to The eCTD Backbone File Specification for Study Tagging //www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM163560.pdf	
5.4	**Literature References**	
	Possible Study Types:	
Study Type	**IN-VIVO BE STUDY(IES) with PK ENDPOINTS** (i.e., fasting/fed/sprinkle) 1. Study(ies) meets BE criteria (90% CI of 80-125, C max, AUC) Select 2. EDR Email: Data Files Submitted Select 3. In-Vitro Dissolution Select	
Study Type	**IN-VIVO BE STUDY with CLINICAL ENDPOINTS** Division of Clinical Review Consult Complete ☐ Yes ☐ No	
Study Type	**IN-VITRO BE STUDY(IES)** (i.e., in vitro binding assays) Select 1. Study(ies) meets BE criteria (90% CI of 80-125) Select 2. EDR Email: Data Files Submitted Select 3. In-Vitro Dissolution Select	

Study Type	**NASALLY ADMINISTERED DRUG PRODUCTS** **Refer to the attached links for Nasal Product BE Tables:** http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM209446.pdf **AND** http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM271017.pdf Division of Bioequivalence Consult Complete ☐ Yes ☐ No	
Study Type	**IN-VIVO BE STUDY(IES) with PD ENDPOINTS** (e.g., topical corticosteroid vasoconstrictor studies) Division of Bioequivalence Consult Complete ☐ Yes ☐ No	
Study Type	**TRANSDERMAL DELIVERY SYSTEMS** Division of Clinical Review Consult Complete ☐ Yes ☐ No	

Updated 1/24//2014