ANDA FILING CHECKLIST

ANDA:
APPLICANT:
RELATED APPLICATION(S):

DRUG NAME:
DOSAGE FORM:

LETTER DATE:
RECEIVED DATE:

Type II DMF #:
Therapeutic Code:
Archival Copy:
EDR Email:

BASIS OF SUBMISSION:

NDA/ANDA:
FIRM:
RLD:
On Cards: ☐ Yes ☐ No

APPLICATION PROPERTIES

P-IV	☐
EXPEDITED REVIEW REQUEST	☐
MaPP 5240.1 or 5240.3 or GDUFA	☐ Approved ☐ Denied
FIRST GENERIC Received	☐
Market Availability	☐ Rx ☐ OTC
PEPFAR	☐
PET	☐
Product Type	☐ Small Molecule Drug
USP Drug Product (at time of filing review)	☐

**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:

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

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

1. Edit Application Property Type in DARRTS
2. Edit Submission Patent Records
   ☐ 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 Obligations Met (Filing Fee, Type II DMF Fee, and Facility Fee)
   ☐ Yes
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) (original signature) **Electronic, Fillable Copy** (if a signed, scanned copy is provided) 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*****	
		Form FDA 3794 (PDF) GDUFA	
1.2	*	**Cover Letter** **Is the drug product subject to REMS requirements?** ☐ Yes ☐ No	
	1.2.1	**Form FDA 3674 (PDF)** 42 U.S.C. 282(j)(5)(B) **Electronic, Fillable Copy** (if a signed, scanned copy is provided)	
*	*	**Table of Contents** (paper submission only)	
1.3	1.3.1	**Contact/Sponsor/Applicant Information** **1.3.1.2 U.S. Agent Appointment Letter** 21 CFR §314.50(a)(5) If the applicant identifies a U.S. Agent on the 356h, a U.S. Agent Appointment letter should be provided.	
	1.3.2	**Field Copy Certification** 21 CFR §314.94(d)(5) (Original Signature)	
	1.3.3	**Debarment Certification** Generic Drug Enforcement Act (GDEA)/ Other: (no qualifying statement) FD&C Act §306(k), §306(a) and (b) (21 U.S.C. 335a(k), 335(a) and (b)) 1. Debarment Certification (original signature) 2. List of Convictions statement (original signature)	
	1.3.4	**Financial Certifications** 21 CFR §54 | 21 CFR §54.2(e) | 21 CFR §314.94(a)(13) Bioavailability/Bioequivalence Financial Certification (Form FDA 3454) Disclosure Statement (Form FDA 3455)	
	1.3.5	**Patent and exclusivity** **1.3.5.1 Patent Information** 21 CFR §314.94(a)(12) | FD&C Act 505(j)(2)(A)(vii) Patents listed for the RLD in the Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations **1.3.5.2 Patent Certification** 21 CFR §314.94(a)(12)(i)(A)(1) through (4) or §314.94(a)(12)(iii) 1. Patent number(s) 2. Paragraph: (Check all certifications that apply) No Relevant Patents ☐ 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? b. Expiration of Pediatric Exclusivity? **1.3.5.3 Exclusivity Claim** Exclusivity Statement: State marketing intentions?	
1.4	1.4.2	**Statement of right of references** 21 CFR §314.50(g)(1) DMF Written Statement of authorization for reference (copy of LoA received from DMF holders) 1. Type II DMF authorization letter(s) or synthesis for Active Pharmaceutical Ingredient 2. Type II DMF# 3. Type III DMF authorization letter(s) for container closure 4. Type III or V DMF authorization letter(s) for sterile product sterilization process	
1.12	1.12.4	**Request for Comments and Advice** – Proprietary name requested If Yes, did the firm provide the request as a separate electronic amendment labeled "Proprietary Name Request" at initial time of filing 1. Yes 2. No – contact the firm to submit the request as a separate electronic amendment	

	1.12.11	**Basis for Submission** 21 CFR §314.94(a)(3) NDA # Ref Listed Drug: Firm: **ANDA suitability petition required?** 21 CFR §10.20 | 21 CFR §10.30 | 21 CFR §314.93 If Yes, provide petition number and copy of FDA's correspondence approving the petition (21 CFR §314.94(a)(3)(iii)) **ANDA Citizen's Petition required?** 21 CFR §10.25(a) | 21 CFR §10.30 | 21 CFR §314.122 If Yes, provide petition number and copy of petition	
	1.12.12	**Comparison between Generic Drug and RLD** 505(j)(2)(A) | 21 CFR §314.94(a)(4) to (6) 1. Conditions of Use 2. Active Ingredients 3. Inactive Ingredients (21 CFR §314.94(a)(9)(ii)) 4. Route of Administration 5. Dosage Form 6. Strength	
	1.12.14	**Environmental Analysis** 21 CFR §25.31 and §25.15(d), if applicable Environmental Assessment (EA) (21 CFR §25.20) If applicable, Environmental Impact Statement (EIS) (21 CFR 25.22) Claim of Categorical Exclusion (21 CFR §25.30 or 21 CFR §25.31)	
	1.12.15	**Request for Waiver** 21 CFR 320.22 | 320.24(b)(6) Request for Waiver of In-Vivo BA/BE Study(ies)	
1.14	1.14.1	**Draft Labeling** (Multi Copies N/A for E-Submissions) 21 CFR 314.94(a)(8)(ii) **1.14.1.1 Draft carton and container labels** 4 copies of draft for paper submission only (each strength and container) **1.14.1.2 Annotated draft labeling text** 21 CFR §314.94(a)(8)(iv) 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 Draft labeling text** 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	
	1.14.3	**Listed Drug Labeling** **1.14.3.1 Annotated comparison with listed drug** 21 CFR §314.94(a)(8)(iv) 1 side by side labeling (package and patient insert) comparison with all differences visually highlighted and annotated **1.14.3.3 Labeling text for reference listed drug** RLD package insert, 1 RLD container label, and if applicable, 1 RLD outer container label	

MODULE 2: CTD SUMMARIES

		COMMENT(S)
2.3	**Quality Overall Summary (QOS)** **E-Submission: PDF** **Word Processed, e.g., MS Word** **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)** **2.3.S Drug Substance (Active Pharmaceutical Ingredient)** 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 2.3.S.6 Container Closure System 2.3.S.7 Stability **2.3.P Drug Product** 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 and Materials 2.3.P.7 Container Closure System 2.3.P.8 Stability	

		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 below for tables specifically designed for in-vitro binding studies **** http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM364105.pdf **E-Submission: PDF** **Word Processed: e.g., MS Word** **2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods** **2.7.1.1 Background and Overview** Table 1. Submission Summary Table 4. Bioanalytical Method Validation Table 6. Formulation Data Table 10. Study Information Table 11. Product Information Table 17. Comparative Physiochemical Data of Ophthalmic Solution Products **2.7.1.2 Summary of Results of Individual Studies** Table 5. Summary of In Vitro Dissolution (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 Table 12. Dropout Information Table 13. Protocol Deviation Table 14. Summary of Standard Curve and QC Data for Bioequivalence Sample Analysis **2.7.1.3 Comparison and Analyses of Results Across Studies** Table 2. Summary of Bioavailability (BA) Studies 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 Table 16. Composition of Meal Used in Fed Bioequivalence Study **2.7.1.4 Appendix** Table 15. SOPs Dealing with Bioanalytical Repeats of Study Samples **2.7.4 Summary of Clinical Safety** **2.7.4.1.3 Demographic and Other Characteristics of Study Population** Table 7. Demographic Profile of Subjects Completing the Bioequivalence Study **2.7.4.2.1.1 Common Adverse Events** Table 8. Incidence of Adverse Events in Individual Studies	

MODULE 3: QUALITY

3.2.S DRUG SUBSTANCE (Active Pharmaceutical Ingredient)

		COMMENT(S)
3.2.S.1	**General Information** (Do not refer to DMF) **3.2.S.1.1 Nomenclature** **3.2.S.1.2 Structure** **3.2.S.1.3 General Properties**	
3.2.S.2	**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) 2. Contact name, phone and fax numbers, email address 3. U.S. Agent's Name (if applicable) 4. Specify function or responsibility 5. Type II DMF number(s) for API(s) 6. CFN, FEI, or DUNS number (if available) 7. Additional sources of API and information (1 through 6) as applicable	
3.2.S.3	**Characterization** All potential impurities should be listed in tabular format as follows: IUPAC Chemical Name | Code # | Chemical Structure | Process/ Degradation Impurity | Source/ Mechanism http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf	

Control of Drug Substance (Active Pharmaceutical Ingredient)

3.2.S.4	3.2.S.4.1	**Specification** Testing specifications and data from drug substance manufacturer(s)	
	3.2.S.4.2	**Analytical Procedures**	
	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) 1. Spectra and chromatograms for **reference standards** and **test samples** 2. Samples-Statement of Availability and Identification (21 CFR §314.50(e)(1)) a. Drug Substance b. API lot numbers	
	3.2.S.4.4	**Batch Analysis** 1. COAs specifications and test results from drug substance manufacturer(s) 2. Drug Product manufacturer's Certificates of analysis	
	3.2.S.4.5	**Justification of Specification** Provide data in tabular format: Chemical Name | Code # | MDD | IT | QT | TDI of Impurity | Proposed AC for Unspecified Impurities | Proposed AC for Specified Impurities | Justification if AC>QT for Specified Impurities http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf	
3.2.S.5		**Reference Standards or Materials** (Do NOT refer to DMF)	
3.2.S.6		**Container Closure Systems**	
3.2.S.7		**Stability** 1. Retest date or expiration date of API(s)	

MODULE 3: QUALITY (cont.)

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) 2. Inactive ingredients and amounts are appropriate per IIG (per/dose justification) (provide justification in a tabular format) 3. Conversion from % to mg/dose values for inactive ingredients (if applicable) 4. Elemental iron: provide daily elemental iron calculation or statement of adherence to 21 CFR 73.1200 (calculation of elemental iron intake based on **maximum daily dose (MDD)** of the drug product is preferred if this section is applicable) 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	
3.2.P.2	**Pharmaceutical Development** 1. Pharmaceutical Development Report 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 Manufacturer(s)** Must correlate to the establishment information submitted in annex to Form 356h for the finished dosage manufacturer and all outside contract testing laboratories. 1. Name and Full Address(es) of the Facility(ies) 2. Contact name, phone and fax numbers, email address 3. U.S. Agent's name (if applicable) 4. Specify function or responsibility 5. cGMP Certification (from both applicant and drug product manufacturer, if different entities) 6. CFN, FEI, or DUNS numbers (if available)	
3.2.P.3.2	**Batch Formula**	
3.2.P.3.3	**Description of Manufacturing Process and Process Controls** 1. Description of the Manufacturing Process and (for aseptic fill products) Facility 2. Master Production Batch Record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified 3. Master Packaging Records for intended marketing container(s) 4. If sterile product 5. Reprocessing Statement (cite 21 CFR 211.115, submitted by the drug product manufacturer and the applicant, if different entities)	
3.2.P.3.4	**Controls of Critical Steps and Intermediates**	
3.2.P.3.5	**Process Validation and/or Evaluation** 1. Terminally Sterilized Product • Validation of production terminal sterilization process • Validation of depyrogenation of all product containers and closures • Validation of container-closure package integrity • Holding Periods 2. Aseptically Filled Product • 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 • Holding Periods • Action taken after a media fill failure	

Controls of Excipients (Inactive Ingredients)

3.2.P.4	*	Source of Inactive Ingredients Identified
	3.2.P.4.1	**Specifications** 1. Testing specifications (including identification and characterization) 2. Supplier's COA (specifications and test results)
	3.2.P.4.2	**Analytical Procedures**
	3.2.P.4.3	**Validation of Analytical Procedures**
	3.2.P.4.4	**Justification of Specifications** (asapplicable) 1. Applicant COA 2. Residual solvents statement(s) from manufacturer(s) 3. Bovine spongiform encephalopathy (BSE) statement (as applicable) 4. Transmissible spongiform encephalopathy (TSE) statement (as applicable) 5. Melamine Certifications statement (as applicable)

Controls of Drug Product

3.2.P.5	3.2.P.5.1	**Specification(s)**
	3.2.P.5.2	**Analytical Procedures**
	3.2.P.5.3	**Validation of Analytical Procedures** (if using USP procedure, must provide verification of USP procedure) Samples - Statement of Availability and Identification (21 CFR §314.50(e)(1)) 1. Finished Dosage Form 2. Lot numbers and strength of Drug Products
	3.2.P.5.4	**Batch Analysis** Certificates of Analysis for Finished Dosage Form
	3.2.P.5.5	**Characterization of Impurities** Provide in tabular format as below: IUPAC Chemical Name | Code # | Chemical Structure | Degradation Impurity | Source/ Mechanism http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf
	3.2.P.5.6	**Justification of Specifications Select** Provide data in tabular format: Chemical Name | Code# | MDD | IT | QT | TDI of Degradation Product | Proposed AC for Unspecified Degradation Product | Proposed AC for Specified Degradation Product | Justification if AC>QT for Degradation Product http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM380338.pdf
3.2.P.7		**Container Closure System** 1. Summary of Container/Closure System (if new resin, provide data) 2. Components Specification and Test Data 3. Packaging Configurations and Sizes 4. Container/Closure Testing (recommended additional testing for all plastic) a. Solid Orals: water permeation, light transmission b. Liquids: leachables, extractables, light transmission 5. Source of supply and suppliers address

		Stability	
3.2.P.8	3.2.P.8.1	**Stability Summary and Conclusion (Finished Dosage Form)** 1. Stability Protocol Submitted 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** 1. Post-Approval Protocol and Commitment (From Applicant and Drug Product Manufacturer, if different entities)	
	3.2.P.8.3	**Stability Data** (Refer to the Final Guidance for Industry *ANDAs: Stability Testing Drug Substances and Products*, dated June 2013) 1. 3 batches? a. Two API lots used? 2. Additional stability data to support additional API sources, if proposed 3. Data- At minimum, 6 months **and** 3 time points a. Accelerated 1. Significant change occurred 2. If yes, 6 months intermediate stability data b. Long term storage (Room Temperature) 4. Batch numbers on stability records the same as the test batch 5. Date accelerated stability study initiated 6. Date accelerated stability sample removed from stability chamber for each testing time point 7. For liquid and semi-solid products, upright and inverted/horizontal storage orientation	

3.2.R REGIONAL INFORMATION 21 CFR §314.50(d)(1)(ii)(b)

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

REGIONAL INFORMATION (DRUG PRODUCT)			
3.2.R.P Drug Product	3.2.R.1.P	**1. Executed Batch Records** **Two (2) Pilot Scales and one (1) Small Scale OR Three (3) Pilot scales (Refer to batch size and packaging information** that meet the minimum threshold amount for specified dosage forms (solid oral dosage forms, oral powders/solutions/suspensions, parenteral drug products, ophthalmic/otic drug products, transdermal patches, topicals (e.g. creams/lotions/gels and inhalation solutions/nasal sprays, etc). Refer to FDA's guidance for industry, *ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers*. (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM366082.pdf) Copies of Executed Batch Records with Equipment Specified, including Packaging Records (Packaging and Labeling Procedures) Batch Reconciliation and Label Reconciliation a. Theoretical Yield b. Actual Yield c. Packaged Yield Bulk Package Reconciliation for all bulk packaging considered a commercial container is recommended 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) b. Bulk Package Stability (3.2.P.8) 1. If bulk is to be shipped, provide accelerated stability data at 0,3,6 months 2. If bulk is only warehoused for repackaging, provide RT stability data at 0,3,6 months c. Bulk Package Container and Closure information (3.2.P.7) **2. Information on Components**	
	3.2.R.2.P	**Comparability Protocols**	
	3.2.R.3.P	**Methods Validation Package** 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**	
5.3	5.3.1	**Bioavailability/Bioequivalence** 1. **Formulation data same?** a. Comparison of all Strengths (proportionality of multiple strengths) 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 http://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, Cmax , AUC) 2. In-Vitro Dissolution	
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) 1. Study(ies) meets BE criteria (90% CI of 80-125) 2. In-Vitro Dissolution	
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	

Effective as of 06/20/2014 and supersedes any previous checklists.

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
Draft Guidance for Industry ANDA Submissions – Content and Format of Abbreviated New Drug Applications:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400630.pdf