

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207844Orig1s000

**ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS**

EXCLUSIVITY SUMMARY

NDA # 207844

SUPPL # Not Applicable

HFD # 520

Trade Name: ALBENZA Chewable Tablets 200 mg

Generic Name: (albendazole)

Applicant Name: Amedra Pharmaceuticals LLC

Approval Date: June 11, 2015

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES NO

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3, SE4, SE5, SE6, SE7, SE8

505(b)(1)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES NO

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

This NDA provides for a new dosage form, a chewable tablet. No new clinical studies were conducted to support this change in dosage form. The Applicant did complete two pivotal bioequivalence studies comparing the approved tablet to the new "chewable" tablet dosage form to support this change. The Applicant owns the approved tablet dosage form, NDA 20666.

(b)(4)/13/186-A Randomized, Open, Label, Balanced, Two-Treatment, Three-Period, Three-Sequence, Single Dose, Reference, Replicated, Crossover, Bioequivalence Study of Albendazole Chewable Tablets, 200 mg of Amedra Pharmaceuticals, LLC USA in Normal, Health, Adult, Human, Subjects under

Fed Condition.

And

(b) (4)/13/187-A Randomized, Open, Label, Balanced, Two-Treatment, Three-Period, Three-Sequence, Single Dose, Reference Replicated, Crossover, Bioequivalence Study of Albendazole Chewable Tablets, 200 mg of Amedra Pharmaceuticals LLC, USA in Normal, Healthy, Adult, Human Subjects under Fed Conditions.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

Not Applicable

d) Did the applicant request exclusivity?

YES NO

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

e) Has pediatric exclusivity been granted for this Active Moiety?

YES NO

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES NO

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES

(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #.

NDA# 20666 ALBENZA (albendazole) Tablets 200 mg

NDA#

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES NO

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary

should only be answered "NO" for original approvals of new molecular entities.)
IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of summary for that investigation.

YES NO

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES NO

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES NO

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES NO

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES NO

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES NO

Investigation #2 YES NO

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1 !
IND # YES ! NO
! Explain:

Investigation #2 !

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05; removed hidden data 8/22/12

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GREGORY F DIBERNARDO
06/11/2015

SUMATHI NAMBIAR
06/11/2015

ACTION PACKAGE CHECKLIST

| APPLICATION INFORMATION ¹ | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NDA # 207844 | NDA Supplement # Not Applicable | If NDA, Efficacy Supplement Type: Not Applicable <i>(an action package is not required for SE8 or SE9 supplements)</i> |
| Proprietary Name: ALBENZA Established/Proper Name: (albendazole) Dosage Form: Chewable Tablet 200 mg | | Applicant: Amedra Pharmaceuticals LLC Agent for Applicant (if applicable): Not Applicable |
| RPM: Gregory F. DiBernardo | | Division: Anti-Infective Products |
| NDA Application Type: <input checked="" type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2) BLA Application Type: <input type="checkbox"/> 351(k) <input type="checkbox"/> 351(a) Efficacy Supplement: <input type="checkbox"/> 351(k) <input type="checkbox"/> 351(a) | | <p style="margin: 0;"><u>For ALL 505(b)(2) applications, two months prior to EVERY action:</u></p> <ul style="list-style-type: none"> Review the information in the 505(b)(2) Assessment and submit the draft² to CDER OND IO for clearance. Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity) <p style="margin: 0;"> <input type="checkbox"/> No changes <input type="checkbox"/> New patent/exclusivity <i>(notify CDER OND IO)</i> Date of check: </p> <p style="margin: 0;"><i>Note: If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</i></p> |
| ❖ Actions | | |
| <ul style="list-style-type: none"> Proposed action User Fee Goal Date is June 11, 2015 | | <input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR |
| <ul style="list-style-type: none"> Previous actions <i>(specify type and date for each action taken)</i> | | <input checked="" type="checkbox"/> None |
| ❖ If accelerated approval or approval based on efficacy studies in animals, were promotional materials received? Note: Promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____ | | <input type="checkbox"/> Received |
| ❖ Application Characteristics ³ | | |

¹ The **Application Information** Section is (only) a checklist. The **Contents of Action Package** Section (beginning on page 2) lists the documents to be included in the Action Package.

² For resubmissions, 505(b)(2) applications must be cleared before the action, but it is not necessary to resubmit the draft 505(b)(2) Assessment to CDER OND IO unless the Assessment has been substantively revised (e.g., new listed drug, patent certification revised).

³ Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA.

Review priority: **Standard** Priority
 Chemical classification (new NDAs only): **3S**
(confirm chemical classification at time of approval)

- | | |
|--------------------------------------------------------------------|---------------------------------------------------|
| <input type="checkbox"/> Fast Track | <input type="checkbox"/> Rx-to-OTC full switch |
| <input type="checkbox"/> Rolling Review | <input type="checkbox"/> Rx-to-OTC partial switch |
| <input checked="" type="checkbox"/> Orphan drug designation | <input type="checkbox"/> Direct-to-OTC |
| <input type="checkbox"/> Breakthrough Therapy designation | |

NDAs: Subpart H

- Accelerated approval (21 CFR 314.510)
 Restricted distribution (21 CFR 314.520)

Subpart I

- Approval based on animal studies

- Submitted in response to a PMR
 Submitted in response to a PMC
 Submitted in response to a Pediatric Written Request

BLAs: Subpart E

- Accelerated approval (21 CFR 601.41)
 Restricted distribution (21 CFR 601.42)

Subpart H

- Approval based on animal studies

- REMS: MedGuide
 Communication Plan
 ETASU
 MedGuide w/o REMS
 REMS not required

Comments:

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 <i>(approvals only)</i> Not Applicable | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| ❖ Public communications <i>(approvals only)</i> | |
| • Office of Executive Programs (OEP) liaison has been notified of action | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| • Indicate what types (if any) of information were issued | <input checked="" type="checkbox"/> None <input type="checkbox"/> FDA Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other |
| ❖ Exclusivity | |
| • Is approval of this application blocked by any type of exclusivity (orphan, 5-year NCE, 3-year, pediatric exclusivity)? • If so, specify the type | <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes |
| ❖ Patent Information (NDAs only) | |
| • Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. | <input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic. |
| CONTENTS OF ACTION PACKAGE | |
| Officer/Employee List | |
| ❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list <i>(approvals only)</i> | <input checked="" type="checkbox"/> Included |
| Documentation of consent/non-consent by officers/employees | <input checked="" type="checkbox"/> Included |

| Action Letters | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ❖ Copies of all action letters (including approval letter with final labeling) | Action and date AP, 6/11/15 |
| Labeling | |
| ❖ Package Insert (write submission/communication date at upper right of first page of PI) | |
| <ul style="list-style-type: none"> Most recent draft labeling (if it is division-proposed labeling, it should be in track-changes format) | <input checked="" type="checkbox"/> Included 6/9/15 |
| <ul style="list-style-type: none"> Original applicant-proposed labeling | <input checked="" type="checkbox"/> Included 6/19/14 |
| ❖ Medication Guide/Patient Package Insert/Instructions for Use/Device Labeling (write submission/communication date at upper right of first page of each piece) | <input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input type="checkbox"/> Device Labeling <input checked="" type="checkbox"/> None |
| <ul style="list-style-type: none"> Most-recent draft labeling (if it is division-proposed labeling, it should be in track-changes format) | <input type="checkbox"/> Included |
| <ul style="list-style-type: none"> Original applicant-proposed labeling | <input type="checkbox"/> Included |
| ❖ Labels (full color carton and immediate-container labels) (write submission/communication date on upper right of first page of each submission) | |
| <ul style="list-style-type: none"> Most-recent draft labeling | <input checked="" type="checkbox"/> Included 11/12/14 |
| ❖ Proprietary Name | Letter: 10/9/14 |
| <ul style="list-style-type: none"> Acceptability/non-acceptability letter(s) (indicate date(s)) Review(s) (indicate date(s)) | Review: 10/7/14 |
| ❖ Labeling reviews (indicate dates of reviews) | RPM: 10/22/14 DMEPA: 10/17/14 & 11/21/14 DMPP/PLT (DRISK): <input checked="" type="checkbox"/> None OPDP: 2/24/15 SEALD: <input checked="" type="checkbox"/> None CSS: <input checked="" type="checkbox"/> None Product Quality <input checked="" type="checkbox"/> None Other: <input checked="" type="checkbox"/> None |
| Administrative / Regulatory Documents | |
| ❖ RPM Filing Review ⁴ /Memo of Filing Meeting (indicate date of each review) | 10/16/14 |
| ❖ All NDA 505(b)(2) Actions: Date each action cleared by 505(b)(2) Clearance Committee | <input checked="" type="checkbox"/> Not a (b)(2) |
| ❖ NDAs only: Exclusivity Summary (signed by Division Director) | <input checked="" type="checkbox"/> Included 6/11/15 |
| ❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm | |
| <ul style="list-style-type: none"> Applicant is on the AIP | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |

⁴ Filing reviews for scientific disciplines are NOT required to be included in the action package.

| | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> This application is on the AIP <ul style="list-style-type: none"> If yes, Center Director's Exception for Review memo (<i>indicate date</i>) If yes, OC clearance for approval (<i>indicate date of clearance communication</i>) | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not an AP action |
| ❖ Pediatrics (<i>approvals only</i>) <ul style="list-style-type: none"> Date reviewed by PeRC _____ If PeRC review not necessary, explain: <u>Has Orphan Product Designation</u> | Not Applicable |
| ❖ Outgoing communications: letters, emails, and faxes considered important to include in the action package by the reviewing office/division (e.g., clinical SPA letters, RTF letter, etc.) (<i>do not include previous action letters, as these are located elsewhere in package</i>) | 2014: 6/26, 8/8, 8/13, 9/11, 10/16, 10/24, 11/7, 11/13, 11/21, 12/19; 2015: 2/26, 3/26, 4/16, 6/8 |
| ❖ Internal documents: memoranda, telecons, emails, and other documents considered important to include in the action package by the reviewing office/division (e.g., Regulatory Briefing minutes, Medical Policy Council meeting minutes) | None |
| ❖ Minutes of Meetings <ul style="list-style-type: none"> If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>) Pre-NDA/BLA meeting (<i>indicate date of mtg</i>) EOP2 meeting (<i>indicate date of mtg</i>) Mid-cycle Communication (<i>indicate date of mtg</i>) Late-cycle Meeting (<i>indicate date of mtg</i>) Other milestone meetings (e.g., EOP2a, CMC focused milestone meetings) (<i>indicate dates of mtgs</i>) | <input checked="" type="checkbox"/> Not Applicable or no mtg <input checked="" type="checkbox"/> No mtg <input checked="" type="checkbox"/> No mtg <input checked="" type="checkbox"/> Not Applicable <input checked="" type="checkbox"/> Not Applicable <input checked="" type="checkbox"/> Not Applicable |
| ❖ Advisory Committee Meeting(s) <ul style="list-style-type: none"> Date(s) of Meeting(s) | <input checked="" type="checkbox"/> No AC meeting |
| Decisional and Summary Memos | |
| ❖ Office Director Decisional Memo (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> None |
| Division Director Summary Review (<i>indicate date for each review</i>) | 6/11/15 |
| Cross-Discipline Team Leader Review (<i>indicate date for each review</i>) | 4/23/15 |
| PMR/PMC Development Templates (<i>indicate total number</i>) | <input checked="" type="checkbox"/> None |
| Clinical | |
| ❖ Clinical Reviews <ul style="list-style-type: none"> Clinical Team Leader Review(s) (<i>indicate date for each review</i>) Clinical reviews (<i>indicate date for each review</i>) Social scientist review(s) (if OTC drug) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review 2/21/15 <input checked="" type="checkbox"/> None |
| ❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not (<i>indicate date of review/memo</i>) | 8/7/14 Clinical filing checklist |
| ❖ Clinical reviews from immunology and other clinical areas/divisions/Centers (<i>indicate date of each review</i>) | <input checked="" type="checkbox"/> None |
| ❖ Controlled Substance Staff review(s) and Scheduling Recommendation (<i>indicate date of each review</i>) | <input checked="" type="checkbox"/> Not Applicable |

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| ❖ Risk Management <ul style="list-style-type: none"> REMS Documents and REMS Supporting Document (<i>indicate date(s) of submission(s)</i>) REMS Memo(s) and letter(s) (<i>indicate date(s)</i>) Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>) | <input checked="" type="checkbox"/> Not Applicable <input checked="" type="checkbox"/> Not Applicable <input checked="" type="checkbox"/> None |
| ❖ OSI Clinical Inspection Review Summary(ies) (<i>include copies of OSI letters to investigators</i>) | <input checked="" type="checkbox"/> None requested |
| Clinical Microbiology <input type="checkbox"/> None | |
| ❖ Clinical Microbiology Team Leader Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| Clinical Microbiology Reviews (<i>indicate date for each review</i>) | 12/01/14 |
| Biostatistics <input type="checkbox"/> None | |
| ❖ Statistical Division Director Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| Statistical Team Leader Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| Statistical Reviews (<i>indicate date for each review</i>) | 4/14/15 |
| Clinical Pharmacology <input type="checkbox"/> None | |
| ❖ Clinical Pharmacology Division Director Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| Clinical Pharmacology Team Leader Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| Clinical Pharmacology review(s) (<i>indicate date for each review</i>) | 4/21/15 |
| ❖ OSI Clinical Pharmacology Inspection Review Summary (<i>include copies of OSI letters</i>) | 4/22/15 |
| Nonclinical <input type="checkbox"/> None | |
| ❖ Pharmacology/Toxicology Discipline Reviews | |
| • ADP/T Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| • Supervisory Review(s) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No separate review |
| • Pharm/tox review, including referenced IND reviews (<i>indicate date for each review</i>) | 5/18/15 |
| ❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> None |
| ❖ Statistical review(s) of carcinogenicity studies (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> No carc |
| ❖ ECAC/CAC report/memo of meeting | <input checked="" type="checkbox"/> None Included in P/T review, page |
| ❖ OSI Nonclinical Inspection Review Summary (<i>include copies of OSI letters</i>) | <input checked="" type="checkbox"/> None requested |
| Product Quality <input type="checkbox"/> None | |
| ❖ Product Quality Discipline Reviews | |
| • Tertiary review (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> None |
| • Secondary review (e.g., Branch Chief) (<i>indicate date for each review</i>) | <input checked="" type="checkbox"/> None |
| • Integrated Quality Assessment (contains the Executive Summary and the primary reviews from each product quality review discipline) (<i>indicate date for each review</i>) | 11/13/14, 3/26/15, & 4/23/15 |
| ❖ Reviews by other disciplines/divisions/Centers requested by product quality review team (<i>indicate date of each review</i>) | <input checked="" type="checkbox"/> None |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ❖ Environmental Assessment (check one) (original and supplemental applications) | |
| <input checked="" type="checkbox"/> Categorical Exclusion (<i>indicate review date</i>)(<i>all original applications and all efficacy supplements that could increase the patient population</i>) | 3/26/15 (see page 62) |
| <input type="checkbox"/> Review & FONSI (<i>indicate date of review</i>) | |
| <input type="checkbox"/> Review & Environmental Impact Statement (<i>indicate date of each review</i>) | |
| ❖ Facilities Review/Inspection | |
| <input checked="" type="checkbox"/> Facilities inspections (<i>action must be taken prior to the re-evaluation date</i>) (<i>only original applications and efficacy supplements that require a manufacturing facility inspection(e.g., new strength, manufacturing process, or manufacturing site change)</i>) | <input checked="" type="checkbox"/> Acceptable 4/22/15 Re-evaluation date: <input type="checkbox"/> Withhold recommendation <input type="checkbox"/> Not applicable |

| Day of Approval Activities | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------|
| ❖ For all 505(b)(2) applications: Not Applicable | <input type="checkbox"/> No changes <input type="checkbox"/> New patent/exclusivity (<i>Notify CDER OND IO</i>) |
| • Check Orange Book for newly listed patents and/or exclusivity (including pediatric exclusivity) | |
| • Finalize 505(b)(2) assessment: Not Applicable | <input type="checkbox"/> Done |
| ❖ For Breakthrough Therapy (BT) Designated drugs: Not Applicable | <input type="checkbox"/> Done (<i>Send email to CDER OND IO</i>) |
| • Notify the CDER BT Program Manager | |
| ❖ For products that need to be added to the flush list (generally opioids): Flush List | <input type="checkbox"/> Done |
| • Notify the Division of Online Communications, Office of Communications: Not Applicable | |
| ❖ Send a courtesy copy of approval letter and all attachments to applicant by fax or secure email | <input checked="" type="checkbox"/> Done |
| ❖ If an FDA communication will issue, notify Press Office of approval action after confirming that applicant received courtesy copy of approval letter: Not Applicable | <input type="checkbox"/> Done |
| ❖ Ensure that proprietary name, if any, and established name are listed in the <i>Application Product Names</i> section of DARRTS, and that the proprietary name is identified as the “preferred” name | <input checked="" type="checkbox"/> Done |
| ❖ Ensure Pediatric Record is accurate: Not Applicable: Has Orphan Product Designation | <input type="checkbox"/> Done |
| ❖ Send approval email within one business day to CDER-APPROVALS | <input checked="" type="checkbox"/> Done |

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

GREGORY F DIBERNARDO
06/11/2015

From: DiBernardo, Gregory
To: Amanda.Martino@impaxlabs.com
Cc: [Nambiar, Sumathi](#); [Adebowale, Abimbola O](#)
Subject: FDA Communication: NDA 207844-ALBENZA Chewable Tablet-Amedra-Request to Submit Revised PI by COB 6/9/15
Date: Monday, June 08, 2015 3:41:00 PM
Attachments: FINAL Request to submit revised PI in response to 4 24 15 submission.pdf
Importance: High

Hello Ms. Martino,

I would like to provide a request for information regarding your April 24, 2015, submission to NDA 207844. Please be aware that there will be no paper/hardcopy communication to follow this email communication.

We are requesting your official submission to the NDA by **June 9, 2015**.

Please let me know if you have questions and please confirm receipt of this communication.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: June 8, 2015

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Amanda Martino Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3588 | Phone number: (301) 796-4063 |
| E-mail: Amanda.Martino@impaxlabs.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 16

Comments: FDA Information Request to submit a revised Package Insert (PI) to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your April 24, 2015, submission we are requesting the following be submitted to NDA 207844:

1. We are requesting you submit a revised Package Insert (PI) for NDA 207844. Please see the attached PI for the FDA proposed revisions. Please note that we have revised the following information:

Under **HIGHLIGHTS OF PRESCRIBING INFORMATION** subsection **WARNINGS AND PRECAUTIONS**

Under **HIGHLIGHTS OF PRESCRIBING INFORMATION** subsection **DRUG INTERACTIONS**

Under **HIGHLIGHTS OF PRESCRIBING INFORMATION** subsection **USE IN SPECIFIC POPULATIONS**

Under **FULL PRESCRIBING INFORMATION: CONTENTS***

Under **FULL PRESCRIBING INFORMATION** subsection **2.1 Dosage**

Under **FULL PRESCRIBING INFORMATION** subsection **2.2 Concomitant Medication to Avoid Adverse Reactions**

Under **FULL PRESCRIBING INFORMATION** subsection **2.3 Monitoring for Safety Before and During Treatment**

Under **FULL PRESCRIBING INFORMATION** subsection **5.3 Risk of Neurologic Symptoms in Neurocysticercosis**

Under **FULL PRESCRIBING INFORMATION** subsection **5.4 Risk of Retinal Damage in Patients with Retinal Neurocysticercosis**

Under **FULL PRESCRIBING INFORMATION** subsection **5.5 Hepatic Effects**

Under **FULL PRESCRIBING INFORMATION** subsection **5.6 Unmasking of Neurocysticercosis in Hydatid Patients**

Under **FULL PRESCRIBING INFORMATION** subsection **6.1 Clinical Trials Experience**

Under **FULL PRESCRIBING INFORMATION** subsection **6.2 Postmarketing Experience**

Under **FULL PRESCRIBING INFORMATION** section **10 OVERDOSAGE**

Under **FULL PRESCRIBING INFORMATION** section **17 PATIENT COUNSELING INFORMATION**

2. We request you use the format ~~strikeout~~ = deleted information and underline = added information as appropriate in your submission. Please include a clean MS Word version and a marked up MS Word version of the PI along with an annotated PDF in your submission.
3. In preparing your response to this request for revised labeling we encourage you to use the “The Selected Requirements for Prescribing Information (SRPI) – a checklist of 42 important format items from labeling regulations (21 CFR 201.56 and 201.57) and guidances on the *PLR Requirements for Prescribing Information* website, to ensure that your proposed PI conforms with format items in regulations and guidances.

Please submit the requested information to the NDA by June 9, 2015.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

13 page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

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/s/

GREGORY F DIBERNARDO

06/08/2015

Information Request to submit a revised package insert (PI)

From: DiBernardo, Gregory
To: Amanda.Martino@impaxlabs.com
Subject: FDA Communication: NDA 207844-ALBENZA Chewable Tablet-Amedra-Request to Submit Revised PI
Date: Thursday, April 16, 2015 1:42:00 PM
Attachments: [04.16.15 Information Request to Submit Revised PI.pdf](#)
Importance: High

Hello Ms. Martino,

I would like to provide a request for information regarding your April 10, 2015, submission to NDA 207844. Please be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions and please confirm receipt of this communication.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: April 16, 2015

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Amanda Martino Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3588 | Phone number: (301) 796-4063 |
| E-mail: Amanda.Martino@impaxlabs.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 14

Comments: FDA Information Request to submit a revised Package Insert (PI) to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your April 10, 2015, submission we are requesting the following be submitted to NDA 207844:

1. We are requesting you submit a revised Package Insert (PI) for NDA 207844. Please see the attached PI for the FDA proposed revisions. Please note that we have revised the following information:

Under subsection **6.1 Clinical Trials Experience**, Table 2 the numbers have been revised

Under subsection **8.4 Pediatric Use**, please note revisions to language

Under subsection **8.5 Geriatric Use**, please note revisions to language

2. We request you use the format ~~strikeout~~ = deleted information and underline = added information as appropriate in your submission. Please include a clean MS Word version and a marked up MS Word version of the PI along with an annotated PDF in your submission.
3. In preparing your response to this request for revised labeling we encourage you to use the “The Selected Requirements for Prescribing Information (SRPI) – a checklist of 42 important format items from labeling regulations (21 CFR 201.56 and 201.57) and guidances on the *PLR Requirements for Prescribing Information* website, to ensure that your proposed PI conforms with format items in regulations and guidances.

Please submit the requested information to the NDA by April 24, 2015.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

12 page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

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/s/

GREGORY F DIBERNARDO
04/16/2015

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablet-Amedra-Request to submit Revised PI
Date: Thursday, March 26, 2015 3:04:00 PM
Attachments: [Request to submit Revised PI 03.26.15.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide a request for information regarding your March 12, 2015, submission to NDA 207844. Please be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: March 26, 2015

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 15

Comments: FDA Information Request to submit a revised Package Insert (PI) to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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NDA 207844

Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your March 12, 2015, submission we are requesting the following be submitted to NDA 207844:

1. We are requesting you submit a revised Package Insert (PI) for NDA 207844. Please see the attached PI for the FDA proposed revisions.
2. We request you use the format ~~strikeout~~ = deleted information and underline = added information as appropriate in your submission. Please include a clean MS Word version and a marked up MS Word version of the PI along with an annotated PDF in your submission.
3. As noted in 21 CFR 314.126(b), for any drug product, any clinical study that is discussed in this section must be adequate and well-controlled (b) (4)

Please submit the requested information by April 10, 2015.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

13 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

GREGORY F DIBERNARDO
03/26/2015

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablet-Amedra-Request to submit revised label
Date: Thursday, February 26, 2015 3:46:00 PM
Attachments: [Request to submit revised labeling.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide a request for information regarding your January 23, 2015 submission to NDA 207844. Please be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
 Center for Drug Evaluation and Research
 Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: February 26, 2015

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 2

Comments: FDA Information Request to your January 23, 2015, submission to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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NDA 207844

Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your January 23, 2015, submission that included a revised package insert, we would like to request the following information be submitted to NDA 207844:

[REDACTED] (b) (4)

Based on the PLR labeling requirements, this information cannot be located in Section 1.

Please obtain, if possible,

[REDACTED] (b) (4)

[REDACTED] (b) (4)

For more information, please see the Guidance for Industry: Labeling for Human Prescription Drug and Biological Products-Implementing the PLR Content and Format Requirements at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075082.pdf>

Please submit the requested information by March 12, 2015 as a labeling amendment.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

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/s/

GREGORY F DIBERNARDO
02/26/2015



NDA 207844

INFORMATION REQUEST

Amedra Pharmaceuticals LLC
Attention: Michele Roy RN, MS, Senior Director, Regulatory Affairs
2 Walnut Grove Drive
Suite 190
Horsham, PA 19044

Dear Ms. Roy:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Albenza (albendazole) chewable tablets.

We are reviewing the Chemistry, Manufacturing, and Controls section of your submission and have the following comments and information requests. We request a written response by January 16, 2015, in order to continue our evaluation of your NDA.

1. Include an upper and lower limit for the (b) (4) baseline measurement taken before (b) (4). The concern is that if the material from step (b) (4) of the manufacturing process is inappropriately (b) (4) an acceptance criterion of (b) (4) of the target (baseline) will not adequately control the (b) (4).
2. Clarify why in the drug product specification a UV method is used for Content Uniformity as opposed to the HPLC method used for Assay.
3. Clarify the following discrepancy:
 - Section 3.2.P.7 states that for commercial use, Albenza Chewable Tablets, 200 mg, will be packaged in a (b) (4). However, the Draft Carton Container Labels and Section 16.1 of the Annotated Draft Labeling provided in Module 1 of the eCTD (1.14 Labeling) does not indicate that a (b) (4) is intended for commercial use for the Chewable Tablet.
4. Provide updated stability data for primary and supportive stability batches.

If you have any questions, call Navdeep Bhandari, Regulatory Health Project Manager, at (240) 402-3815.

Sincerely,

{See appended electronic signature page}

Rapti D. Madurawe, Ph.D.
Branch Chief, Branch V
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

**Dorota M.
Matecka -S**

Digitally signed by Dorota M.
Matecka -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=13001
23291, cn=Dorota M. Matecka -S
Date: 2014.12.19 16:21:42 -05'00'

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablet-Amedra -Revised Package Insert
Date: Friday, November 21, 2014 3:35:00 PM
Attachments: [Information Request to submit Revised Package Insert.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide you the FDA revised Package Insert (PI) for NDA 207844. Please review the FDA revisions and requests for more information in the attached document. We request your response be submitted officially to the NDA by

December 5, 2014.

Please be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: November 21, 2014

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 2

Comments: FDA Information Request to submit a revised Package Insert to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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NDA 207844

Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your June 19, 2014, submission we are requesting the following be submitted to NDA 207844:

1. We are requesting you submit a revised Package Insert (PI) for NDA 207844. Please see the attached PI for the FDA proposed revisions.
2. We request you use the format ~~strikeout~~ = deleted information and underline = added information as appropriate in your submission. Please include a clean MS Word version and a marked up MS Word version of the PI along with an annotated PDF in your submission.

Please submit the requested information by December 5, 2014.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

13 page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page.

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/s/

GREGORY F DIBERNARDO
11/21/2014

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza (chewable tablet)-Amedra-Follow Up Information Request Re: Filing Communication
Date: Thursday, November 13, 2014 9:46:00 AM
Importance: High

Hello Ms. Roy,

We note on November 5, 2014, you submitted your response to our October 16, 2014, NDA filing communication for NDA 207844 (Filing Communication sent in the email below).

However after reviewing your November 5, 2014, submission we have the additional following request for information:

Please resubmit all XPT datasets with the unique subject ID included as a data field. Please be aware that without this information, your data cannot be analyzed using statistical software.

Please let me know if you have any additional questions.

We request that you submit your response officially to NDA 207844 as soon as possible.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063

From: DiBernardo, Gregory
Sent: Friday, October 17, 2014 12:11 PM
To: Michele Roy (michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza (chewable tablet)-Amedra-Filing Communication
Importance: High

Hello Ms. Roy,

I would like to provide the FDA Filing Communication letter for NDA 207844. Please be aware that this same information will be sent to you through regular U.S. Mail in the next few days.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063

<< File: FINAL No Filing Review Issues Identified (COR-NDAFILE-05).pdf >>

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/s/

GREGORY F DIBERNARDO

11/13/2014

Follow Up Information Request to NDA Filing Communication

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablets-Amedra - Information Request
Date: Friday, November 07, 2014 2:17:00 PM
Attachments: [Product Microbioloy Information Request.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide a request for information for NDA 207844. Please be aware that there will be no paper/hardcopy communication to follow this email communication.

We request your response to be submitted officially to NDA 207844 by November 12, 2014.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
 Center for Drug Evaluation and Research
 Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: November 7, 2014

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 2

Comments: FDA Information Request to your November 5, 2014, submission to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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NDA 207844

Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

In response to your November 5, 2014, submission we would like to request the following information be submitted to NDA 207844:

Microbiology Information Request:

Your November 5, 2014, submission contains information to support a waiver of microbial limits release testing for your drug product. You state that microbial limits testing will be performed on process validation batches and stability batches using methods described in USP ^{(b) (4)}. Microbial limits testing is typically performed using methods described in USP <61> and USP <62>. Clarify which methods you will use for microbial limits testing.

Please submit the requested information by November 12, 2014.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

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/s/

GREGORY F DIBERNARDO
11/07/2014

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablet-Amedra-DMEPA Carton/Container Comments
Date: Friday, October 24, 2014 4:47:00 PM
Attachments: [DMEPA Carton and Container Label Information Request.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide an information request for NDA 207844. Please submit your response officially to NDA 207844. Please also be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: October 24, 2014

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 3

Comments: FDA Information Request to your June 19, 2014, submission to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

We would like to request the following information be submitted to NDA 207844:

1. General recommendations for the carton labeling for Albenza Chewable Tablets, 200 mg, (NDA 207844) (b) (4)



2. Albenza Chewable Tablets, 200 mg, (NDA 207844)

a. Blister Card (6 tablets)

- i. We note that the product strength is presented with no space between numerical dose and unit of measure, and that the unit of measure “MG” is capitalized. Since lower case letters are more commonly used in metric unit abbreviations and that the Dosage Forms and Strengths section of the PI presents the strength as “200 mg” (with lower case ‘mg’), consider revising the product strength “200MG” to read “200 mg” to improve readability and for consistency with the strength presentation in the PI.

b. Carton Labeling for 2 blister cards (12 tablets)

- i. See 2.a.i.
- ii. The strength presentation is located next to the proprietary name which may cause the strength to be misinterpreted as part of the proprietary name. Consider relocating the strength below the proprietary and established names to minimize the risk of the strength being overlooked.

Information Request

- iii. The net quantity (12 tablets) on the carton labeling could be mistaken as strength. Relocate away from the proprietary name, established name, and strength for less prominence (e.g. lower right corner).¹
- c. Wallet Card (b)(4) tablet)
- i. See 2.a.i. and 2.b.ii.
 - ii. There is (b)(4) on the wallet card. Include net quantity (2 tablets) and ensure this net quantity is located away from product strength as described in 2.c.
 - iii. Consider revising the strength statement to “200 mg per chewable tablet” on the principal display panel to avoid misinterpretation of (b)(4) (b)(4). This may be achieved by removing the picture of 2 tablets on the principal display panel.

Please submit the requested information by November 14, 2014.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

¹ Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors. Food and Drug Administration. 2013. Available from <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf>

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/s/

GREGORY F DIBERNARDO
10/24/2014



NDA 207844

**FILING COMMUNICATION –
NO FILING REVIEW ISSUES IDENTIFIED**

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044

Dear Ms. Roy:

Please refer to your New Drug Application (NDA) dated August 11, 2014, received August 11, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Albenza (albendazole) Chewable Tablet, 200 mg.

We also refer to your amendments dated September 5, and 26, 2014.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date we received your application. The review classification for this application is **Standard**. Therefore, the user fee goal date is June 11, 2015.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by May 11, 2015.

At this time, we are notifying you that, we have not identified any potential review issues. Please note that our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

We request that you submit the following information:

Clinical:

1. The five PADER files you have submitted do not suffice as a safety update. Please perform a review of the scientific literature and a search of FAERS reports and submit as a safety update. If any new safety information is identified, please include in your updated product label.
2. Please submit XPT transport files for the clinical AE and laboratory datasets.

Product Quality Microbiology:

Your application proposes a waiver of microbial limits testing for drug product release and stability. Your proposal may be acceptable; however, more information on your process and controls is needed. Please address the following points:

1. Identify and justify critical control points in the manufacturing process that could affect (b) (4) of the drug product, including the maximum holding time for (b) (4).
2. Describe microbiological monitoring and acceptance criteria for the critical control points that you have identified. Conformance to the acceptance criteria established for each critical control point should be documented in the batch record in accordance with 21 CFR 211.188.
 - a. Your application provides a list of excipients for which microbiological testing is performed by your supplier, but you do not provide acceptance criteria. Provide the microbiological acceptance criteria for these excipients.
3. Describe activities taken when microbiological acceptance criteria are not met at control points.

In addition to these points, address the following:

1. Provide the results of microbial limits testing performed on exhibit or stability batches of the drug product.
2. Your application states that historical data from the lead product Albenza® supports a low risk of microbiological growth. These data may be used to support a waiver of microbial limits testing for the chewable tablets, but you should provide these data and a rationale for why they are adequate to represent the microbiological risks of the chewable tablet.
3. Verify the suitability of any microbiological testing methods for use with your drug product.

4. You should minimally perform microbial limits testing at the initial stability testing time point. Provide an updated stability schedule to reflect this testing.

Biopharmaceutics:

1. We could not locate the dissolution method development report within the NDA; if it was included in the original submission, please provide the CTD location. In the event that this report was omitted, provide data that support the suitability and discriminating ability of the proposed dissolution method for your product. If the proposed method is similar to that for the approved oral tablet in NDA 20666, provide a comparison of the two methods, explaining the rationale for any changes that may have been made for the proposed product. The general guidelines for the content of a dissolution method development report are as follows:
 - I. **Dissolution Test:** Include the dissolution method development report supporting the selection of the proposed dissolution test. The dissolution development report should include the following information:
 - a. Solubility data for the drug substance over the physiologic pH range;
 - b. Detailed description of the dissolution test being proposed for the evaluation of your product and the developmental parameters (*i.e., selection of the equipment/apparatus, in vitro dissolution/release media, agitation/rotation speed, pH, assay, sink conditions, etc.*) used to select the proposed dissolution method as the optimal test for your product. If a surfactant is used, include the data supporting the selection of the type and amount of surfactant. The testing conditions used for each test should be clearly specified. The dissolution profile should be complete and cover at least 85% of drug release of the label amount or whenever a plateau (*i.e., no increase over 3 consecutive time-points*) is reached. We recommend use of at least twelve samples per testing variable and sampling time points of 10, 15, 20, 30, 45 60, 90 and 120 min;
 - c. Provide the complete dissolution profile data (*individual, mean, SD, profiles*) for your product. The dissolution data should be reported as the cumulative percentage of drug dissolved with time (*the percentage is based on the product's label claim*);
 - d. Data to support the discriminating ability of the selected dissolution method. In general, the testing conducted to demonstrate the discriminating ability of the selected dissolution method should compare the dissolution profiles of the reference (target) product and the test products that are intentionally manufactured with meaningful variations for the most relevant critical manufacturing variables (*i.e., ± 10-20% change to the specification-ranges of these variables*);
 - e. Supportive validation data for the dissolution method (*i.e., method robustness, etc.*) and analytical method (precision, accuracy, linearity, stability, etc.).

II. Dissolution Acceptance Criterion: For the selection of the dissolution acceptance criterion(a) of your product, the following points should be considered:

- a. The dissolution profile data (15, 20, 30, 45, 60, 90, 120 min; n = 12) from the pivotal clinical batches and primary (registration) batches (throughout the stability program) should be used for the setting of the dissolution acceptance criterion(a) of your product (i.e., specification-sampling time point and specification value).
 - b. The in vitro dissolution profile should encompass the timeframe over which at least 85% of the drug is dissolved or where the plateau of drug dissolved is reached, if incomplete dissolution is occurring.
 - c. The selection of the specification time point should be where Q=80 % dissolution occurs. However, if you have a slowly dissolving product, specifications at two time points may be adequate for your product. The first time point should be selected during the initial dissolution phase (i.e., 15-30 minutes about 40-50% dissolution) and the second time point should be where Q = 80% dissolution occurs.
2. The proposed dissolution acceptance criterion of Q = (b) (4) is neither supported by the release data for batches B130402, B130403 and B130404 nor adequately justified. Your current method results in approximately (b) (4)% albendazole release at the first sampling time point of 15 min, indicative that the method may not be discriminating for potential unacceptable batches. Per the guidelines provided above, please investigate the discriminating power of the proposed method and modify the method and/or the proposed acceptance criterion accordingly. Thereafter, update the Specifications Table to reflect the new dissolution acceptance criterion.
3. Confirm the mode of drug administration in the pivotal bioavailability study ((b) (4)/13/187), i.e., if the test product was chewed or swallowed whole.
4. Please provide Summary Tables for the bioanalytical method validation and its performance in study # (b) (4)/13/187 using the attached template.

Bio-Analytical Method Report Summary In-Study Validation

| | |
|------------------------------------------------------------------|--|
| Matrix | |
| Sample Volume Required, Storage Conditions, Extraction Procedure | |
| Concentration Range | |
| Analytical Methodology | |
| Detection | |
| Regression Type | |
| Coefficient of Determination | |

| | | |
|---------------------------------------|---------------------------------------|--|
| Between-Batch Accuracy | standards QCs | |
| Between-Batch CV | standards QCs | |
| Within-Batch | Accuracy CV | |
| Recovery | Drug Reference | |
| Stability in human plasma | Room temp Freeze/thaw Long term | |
| Solution Stability | at room temp at 4°C | |
| Reference Solution Stability | at room temp at 4°C | |
| LLOQ (Accuracy / CV) | | |
| Processed Stability | at 4°C | |
| Dilution Integrity (v:v sample-blank) | | |

PRESCRIBING INFORMATION

Your proposed prescribing information (PI) must conform to the content and format regulations found at 21 [CFR 201.56\(a\) and \(d\)](#) and [201.57](#). We encourage you to review the labeling review resources on the [PLR Requirements for Prescribing Information](#) website including:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products
- Regulations and related guidance documents
- A sample tool illustrating the format for Highlights and Contents, and
- The Selected Requirements for Prescribing Information (SRPI) – a checklist of 42 important format items from labeling regulations and guidances.

We acknowledge your request for a waiver of the requirement that the Highlights of Prescribing Information be limited to no more than one-half page. We will consider your request during labeling discussions.

PROMOTIONAL MATERIAL

You may request advisory comments on proposed introductory advertising and promotional labeling. Please submit, in triplicate, a detailed cover letter requesting advisory comments (list

each proposed promotional piece in the cover letter along with the material type and material identification code, if applicable), the proposed promotional materials in draft or mock-up form with annotated references, and the proposed package insert (PI). Submit consumer-directed, professional-directed, and television advertisement materials separately and send each submission to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Do not submit launch materials until you have received our proposed revisions to the package insert (PI), and you believe the labeling is close to the final version.

For more information regarding OPDP submissions, please see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>. If you have any questions, call OPDP at 301-796-1200.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the drug product for this indication is seeking to have the orphan drug designation transferred from the previous designee to Amedra Pharmaceuticals, LLC, you will be exempt from this requirement upon the completion of this transfer. However, until such time, you are required to address these pediatric assessments.

We note that you have not addressed how you plan to fulfill this requirement. Within 30 days of the date of this letter, please submit (1) a full waiver request, (2) a partial waiver request and a pediatric development plan for the pediatric age groups not covered by the partial waiver request, or (3) a pediatric drug development plan covering the full pediatric age range. All waiver requests must include supporting information and documentation. A pediatric drug development plan must address the indication(s) proposed in this application.

If you request a full waiver, we will notify you if the full waiver is denied and a pediatric drug development plan is required.

Pediatric studies conducted under the terms of section 505B of the Federal Food, Drug, and Cosmetic Act (the Act) may also qualify for pediatric exclusivity under the terms of section 505A of the Act. If you wish to qualify for pediatric exclusivity please consult Division of Anti-

Infective Products. Please note that satisfaction of the requirements in section 505B of the Act alone may not qualify you for pediatric exclusivity under 505A of the Act.

If you have any questions, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 769-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

SUMATHI NAMBIAR
10/16/2014



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 207844

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Amedra Pharmaceuticals LLC
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044

ATTENTION: Michelle Roy RN, MS
Senior Director, Regulatory Affairs

Dear Ms. Roy:

Please refer to your New Drug Application (NDA), dated and received, June 19, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Albendazole Chewable Tablet, 200 mg.

We also refer to your correspondence, dated and received September 5, 2014, requesting review of your proposed proprietary name, Albenza.

We have completed our review of the proposed proprietary name, Albenza, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your September 5, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301)796-5413. For any other information regarding this application, contact Gregory DiBernardo, Regulatory Project Manager in the Office of New Drugs, at (301)796-4063.

Sincerely,

{See appended electronic signature page}

Kellie A. Taylor, Pharm.D., MPH
Deputy Director
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

TODD D BRIDGES on behalf of KELLIE A TAYLOR
10/09/2014

From: DiBernardo, Gregory
To: [Michele Roy \(michele.roy@amedrapharma.com\)](mailto:michele.roy@amedrapharma.com)
Subject: FDA Communication: NDA 207844-Albenza Chewable Tablet-Amedra-DMEPA IR & Request for Sample
Date: Thursday, September 11, 2014 12:38:00 PM
Attachments: [DMEPA Information Request.pdf](#)
Importance: High

Hello Ms. Roy,

I would like to provide an information request for NDA 207844. Please submit your response officially to NDA 207844. Please also be aware that there will be no paper/hardcopy communication to follow this email communication.

Please let me know if you have questions.

Thank you,

Gregory F. DiBernardo

Regulatory Project Manager

FDA/CDER/OND/OAP/Division of Anti-Infective Products

10903 New Hampshire Avenue

Building 22, Room 6223

Silver Spring, MD 20993

Telephone: (301) 796-4063



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Antimicrobial Products

COMMUNICATION SHEET

DATE: September 11, 2014

| | |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------|
| To: Michele A. Roy, RN, MS Senior Director, Regulatory Affairs | From: Gregory F. DiBernardo Regulatory Project Manager |
| Company: Amedra Pharmaceuticals, LLC | Division of Anti-Infective Products (DAIP) |
| Fax number: Communication sent via E-mail | Fax number: (301) 796-9882 |
| Phone number: (215) 259-3582 | Phone number: (301) 796-4063 |
| E-mail: Michele.roy@amedrapharma.com | |
| Subject: NDA 207844-Albenza (albendazole) Chewable Tablet | |

Total no. of pages including cover: 2

Comments: FDA Information Request to your June 19, 2014, submission to NDA 207844

Confirm receipt of this communication at: gregory.dibernardo@fda.hhs.gov

Document to be mailed: YES NO

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NDA 207844

Information Request

The Division of Anti-Infective Products (DAIP) refers to NDA 207844 for Albenza (albendazole) Chewable Tablet.

We would like to request the following information be submitted to NDA 207844:

1. Please submit a sample of Albenza 200 mg 2 Tablets in 1 Blister Pack (configured as a Wallet Card).
2. Additionally, we noted that the carton labeling states “this carton contains twelve (12) individually sealed tablets in two blister cares of six (6) each. Since the dose for patients weighting 60 kg or greater is 400 mg twice daily, this carton will only provide a 3 days supply. Therefore, we would like you to clarify the rationale for the total packaged quantity for the carton since the treatment duration is 28 days.

Please submit the requested information by September 26, 2014.

If you have questions regarding this communication, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

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/s/

GREGORY F DIBERNARDO
09/11/2014
DMEPA Information Request



NDA 207844

**NDA ACKNOWLEDGEMENT
USER FEES RECEIVED**

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044

Dear Ms. Roy:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for Albenza (albendazole) Chewable Tablet, 200 mg.

You were notified in our letter dated August 8, 2014, that your application was not accepted for filing due to non-payment of fees. This is to inform you that the Agency has received all required fees and your application has been accepted as of August 11, 2014.

Unless we notify you within 60 days of the above date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 10, 2014, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

You are also responsible for complying with the applicable provisions of sections 402(i) and 402(j) of the Public Health Service Act (PHS Act) [42 USC §§ 282 (i) and (j)], which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No, 110-85, 121 Stat. 904).

The NDA number cited above should be included at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, contact Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

MAUREEN P DILLON PARKER
08/13/2014



NDA 207844

UNACCEPTABLE FOR FILING

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044

Dear Ms. Roy:

Please refer to your New Drug Application (NDA) dated June 19, 2014, received June 19, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Albenza (albendazole) Chewable Tablet, 200 mg.

We have not received the appropriate user fee for this application. An application is considered incomplete and cannot be accepted for filing until all fees owed have been paid. Therefore, this application is not accepted for filing. We will not begin a review of this application's adequacy for filing until FDA has been notified that the appropriate fee has been paid. Payment should be submitted to the following address:

Food and Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000

Checks sent by courier should be addressed to:

U.S. Bank
Attention: Government Lockbox 979107
1005 Convention Plaza
St. Louis, MO 63101

When submitting payment for an application fee, include the User Fee I.D. Number, the Application number, and a copy of the user fee coversheet (Form 3397) with your application fee payment. When submitting payment for previously unpaid product and establishment fees, please include the Invoice Number(s) for the unpaid fees and the summary portion of the invoice(s) with your payment. The FDA P.O. Box number (P.O. Box 979107) should be included on any check you submit.

The receipt date for this submission (which begins the review for filability) will be the date the review division is notified that payment has been received by the bank. Please notify the regulatory project manager indicated below when the appropriate user fees have been sent.

Please cite the NDA number listed above at the top of the first page of all submissions to this application. Unless you are using the FDA Electronic Submissions Gateway (ESG), send all submissions by overnight mail or courier to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications.

If you wish to send payment by wire transfer, or if you have any other user fee questions, please call the Prescription Drug User Fee staff at (301) 796-7900.

If you have any questions regarding this application, contact Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

MAUREEN P DILLON PARKER
08/08/2014



NDA 207844

NDA ACKNOWLEDGMENT

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044

Dear Ms. Roy:

We have received your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Albenza (albendazole) Chewable Tablet, 200 mg

Date of Application: June 19, 2014

Date of Receipt: June 19, 2014

Our Reference Number: NDA 207844

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on August 18, 2014, in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

You are also responsible for complying with the applicable provisions of sections 402(i) and 402(j) of the Public Health Service Act (PHS Act) [42 USC §§ 282 (i) and (j)], which was amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No, 110-85, 121 Stat. 904).

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm>.

Secure email between CDER and applicants is useful for informal communications when confidential information may be included in the message (for example, trade secrets or patient information). If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov. Please note that secure email may not be used for formal regulatory submissions to applications. If you have any questions, call Mr. Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Maureen P. Dillon-Parker
Chief, Project Management Staff
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

MAUREEN P DILLON PARKER
06/26/2014