CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207844Orig1s000

CHEMISTRY REVIEW(S)

NDA 207844

Albenza (albendazole) Chewable Tablets

Amedra Pharmaceuticals LLC

Caroline Strasinger, Ph.D.

Review Chemist

Office of New Drug Quality Assessment
Division of New Drug Quality Assessment II
Branch V

CMC Review of NDA 207844
For the Division of Anti-Infective Products

Reference ID: 3781820

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Chemistry Review Data Sheet

1. NDA 207844

2. REVIEW #: #1

3. REVIEW DATE: 29-JAN-2015

4. REVIEWERS:

Primary:

Reviewer	NDA CTD Section
Caroline Strasinger, Ph.D.	Drug Substance Drug Product

Secondary:

Reviewer	Section
Dorota Matecka, Ph.D.	Drug Substance
	Drug Product

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
N/A	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	19-JUN-2014
Amendment 0002	11-AUG-2014
Amendment 0009	19-DEC-2014
Amendment 0010	16-JAN-2015

7. NAME & ADDRESS OF APPLICANT:

Reference ID: 3781820

Chemistry Review Data Sheet

Name:	Amedra, LLC
Address:	2 Walnut Grove Drive Suite 190 Horsham, PA 19044
Representative:	Michele Roy RN, MS Senior Director, Regulatory Affairs
Telephone:	215-259-3582

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: ALBENZA
b) Non-Proprietary Name (USAN): albendazole
c) Code Name/#:
d) Chem. Type/Submission Priority:
- Chem. Type: 3
- Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION: 505 (b)(1)

10. PHARMACOL. CATEGORY: treatment of neurocysticercosis

11. DOSAGE FORM: tablet

12. STRENGTH/POTENCY: 200 mg

13. ROUTE OF ADMINISTRATION: Oral (Chewable Tablet)

14. Rx/OTC DISPENSED: _X_Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):
_____SPOTS product – Form Completed

___X__Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Albendazole

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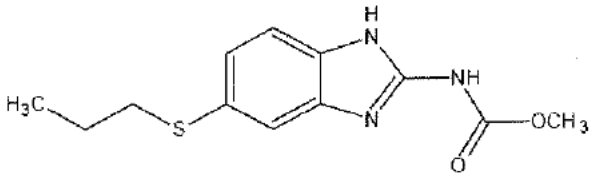

WHO: Methyl 5-(propylthio)-2-benzimidazolcarbamate
USAN: [5-(propylthio)-1H –benzimidazol-2-yl]-, methyl ester

Molecular Formula
$C_{12}H_{15}N_3O_2S$
Relative Molecular Mass
265.3

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	III	(b) (4)	(b) (4)	4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	III			4	N/A	N/A	N/A
	II			3	Adequate	23-SEP-2014	S. Kim for NDA 20666
	IV			1	Adequate	05-MAR-2015	C. Strasinger for NDA 207844
	IV			1	Adequate	08-FEB-2015	C. Strasinger for NDA 207844

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[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	20666	Albenza Tablets

18. STATUS:

ONDQA:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	ACCEPTABLE	26-AUG-14	Office of Compliance
Pharm/Tox	N/A		
Biopharm	PENDING	20-MAR-15	Salaheldin Hamed
LNC	N/A		
Methods Validation	N/A		
DMEPA	N/A		
EA	Claim for categorical exclusion is granted	8-JAN-15	Caroline Strasinger
Microbiology	Adequate	13-NOV-14	Erika Pfeiler

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The Chemistry Review for NDA 207844

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This NDA has provided sufficient information to assure identity, strength, purity, and quality of the drug product.

An overall "Acceptable" recommendation has been made by the Office of Compliance.

Labels and labeling are adequate from a CMC perspective.

Therefore, from the ONDQA perspective, this NDA is recommended for approval.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug product:
Albenza (albendazole) Chewable Tablets, 200 mg, is a round, mottled pink, concave tablet debossed with the product code "ap" above "551" on one side and plain on the other side. The chewable tablets are manufactured, packaged, and release and stability tested at [redacted] (b) (4) Final release of the drug product is the responsibility of **Amedra Pharmaceutical LLC** in **Horsham, PA.** The quality of the drug product is controlled by tests for appearance, identification, assay, related substances, content uniformity, dissolution, and residual moisture.

For commercial use, Albenza Chewable Tablets, 200 mg, will be packaged in [redacted] (b) (4) [redacted] (b) (4) blisters with either peel push, or push through foil lidding. There are two carton configurations; either 12 tablets (containing 6 count blister cards) or a 2 tablet wallet pack. The Applicant is requesting 24 months of expiration dating and it is supported by 12 months of stability data for [redacted] (b) (4) blisters. 24 months of expiry is granted for all packaging configurations.

Drug Substances:

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Albendazole

Drug substance information is referenced to DMF [redacted] (b) (4) An LOA to reference the DMF has been provided. Additionally, the drug substance for this NDA is the same as in approved NDA 20666 for Albenza Tablets. The DMF was deemed adequate by Dr. S. Kim to support NDA 20666 [redacted] (b) (4) on 23-SEP-2014. No additional amendments or annual reports have been added to the DMF since the last review.

The drug substance specifications include tests for appearance, identification, organic impurities, assay, solubility, loss on drying, residue on ignition, related substances, residual solvents, and particle size. Sixty months of long-term and 6 months accelerated stability data were provided in the NDA. The data supports a retest period of [redacted] (b) (4)

B. Description of How the Drug Product is Intended to be Used

Albenza (albendazole) Chewable Tablet, 200 mg is an orally administered chewable tablet and is a well-known broad spectrum anthelmintic for the treatment of neurocysticerosis and cystic hydatid disease of the liver. Dosing will vary depending upon which parasitic infection is being treated. Generally speaking, an adult patient is administered 400 mg twice daily with meals for 8-30 days. Albenza is contraindicated in patients with known hypersensitivity to benzimidazole class of compounds. The Chewable Tablet is to be packaged in either a 6 count blister card or 2 count wallet pack. The product should be stored between 20° and 25°C (68-77°F).

Albenza Chewable Tablet

From Initial Quality Assessment			Review Assessment		
Product attribute/ CQA	**Factors that can impact the CQA**	**Risk Ranking***	**Risk Mitigation approach**	**Risk Evaluation**	**Lifecycle Considerations / Comments****
Assay for Albendazole	Quality of incoming API; analytical procedure	L	Drug Load is 28.6% w/w	Acceptable (L)	None
Physical stability (moisture content)	Stability moisture content; manufacturing [redacted] (b) (4)	M	DS specification in accordance with USP; [redacted] (b) (4)	Acceptable (M)	[redacted] (b) (4)
Content uniformity	Assay analytical procedure	L	By UV per USP	Acceptable (L)	None
Palatability	Formulation; properties and quality of flavoring agents; process	M	[redacted] (b) (4) and wild berry flavor for palatability, (novel excipients)	Acceptable (L)	None

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Chemistry Assessment Section

Microbial limits	Packaging; quality of raw materials	L	(b) (4) Lead product exhibited low microbial activity	Acceptable (L)	Microbiology reviewer found approach acceptable
Impurities including residual solvents	Quality of API and excipients; analytical procedure.	L	Controlled in the Drug Substance and Drug Product	Acceptable (L)	None
Dissolution	Formulation and raw materials; API particle size; Analytical procedure	M	The dissolution method is discriminating towards certain formulation changes and towards tablet (b) (4)	Acceptable (M)	
Hardness	Compatibility of API and excipients; (b) (4)	L	(b) (4) checked) in addition to thickness and friability tests	Acceptable (M)	(b) (4)

C. Basis for Approvability Recommendation

Sufficient information has been provided in the NDA to assure the quality of the drug substances and the drug product. Product Quality Microbiology has recommended approval of the NDA. The Biopharmaceutics Reviewer has indicated that the dissolution method and specifications are acceptable.

The NDA can be recommended for approval from the CMC perspective.

III. Administrative

A. Reviewer's Signature

B. Endorsement Block

ChemistName/Date: Caroline Strasinger, PhD 20-MAR-2015
ChemistryTeamLeaderName/Date: Dorota Matecka, PhD 20-MAR-2015
ProjectManagerName/Date: Navi Bhandari 20-MAR-2015

Caroline Strasinger -A

Digitally signed by Caroline Strasinger -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2600036504B, cn=Caroline Strasinger -A
Date: 2015.03.24 14:50:56 -04'00'

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=1300123291, cn=Dorota M. Matecka -S
Date: 2015.03.26 07:11:04 -04'00'

43 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

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(b) (4)

[redacted]

II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1

A. Labeling & Package Insert

The label for Albenza will be a combined label for the previously approved tablet and the chewable tablet subject of this NDA. The Applicant has requested a waiver for the highlights section.

1. Package Insert

(a) "Highlights" Section

ALBENZA® (albendazole) tablet and chewable tablet, for oral use
Initial U.S. Approval: 1996

----------DOSAGE FORMS AND STRENGTHS----------

- Tablet, 200 mg (3)
- Chewable Tablet, 200 mg (3)

Evaluation:

Item	Comments on the Information Provided in NDA
Drug name (201.57(a)(2))	
Proprietary name and established name	**Satisfactory**
Dosage form, route of administration	Tablet, oral use Satisfactory
Controlled drug substance symbol (if	N/A

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applicable)	
Dosage Forms and Strengths (201.57(a)(8))	Satisfactory
Whether the drug product is scored	Not scored

This section is satisfactory.

The following comment should be conveyed to the Applicant:

(b) "Full Prescribing Information" Section

#3. Dosage Form and Strength

- Tablets, 200 mg
- Chewable Tablets, 200 mg

Evaluation:

Item	Comments on the Information Provided in NDA
Available dosage forms and strengths: in metric system	**Satisfactory**
Active moiety expression of strength with equivalence statement (if applicable)	N/A
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable.	Satisfactory

This section is satisfactory.

#11. Description Section

The following edits (highlights and strikethroughs) have been made to the previously approved ALBENZA label. It was updated to match current USP and current API supplier descriptions.

11 DESCRIPTION

ALBENZA (albendazole) is an orally administered [redacted] (b) (4) anthelmintic. Chemically, it is methyl 5-(propylthio)-2-benzimidazolecarbamate. Its molecular formula is $C_{12}H_{15}N_3O_2S$. Its molecular weight is 265.34. It has the following chemical structure:

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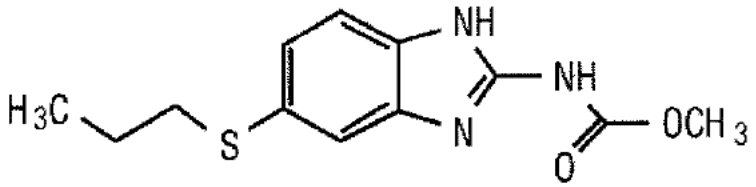

Albendazole is a white to ~~off-white~~ yellowish powder. It is freely soluble in anhydrous formic acid and very slightly soluble in ether and in methylene chloride [redacted] (b) (4) Albendazole is practically insoluble in alcohol and water.

Tablets
Each white to off-white, circular, biconvex, bevel-edged film coated TILTAB tablet is debossed with "ap" and "550" [redacted] (b) (4) and contains 200 mg of albendazole.
Inactive ingredients consist of: carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone, sodium lauryl sulfate, sodium saccharin, sodium starch glycolate, and starch.

Chewable Tablets
Each round, mottled pink, concave chewable tablet is debossed with "ap" above "551" and contains 200 mg of albendazole.
Inactive ingredients consist of: lactose monohydrate, microcrystalline cellulose, D-mannitol, sodium starch glycolate, povidone, N-C Wild Berry Type Flavor, magnesium stearate, crospovidone, polyvinyl acetate, sucralose, colloidal silicone dioxide, sodium lauryl sulfate, D&C Red #30/Helendon Pink Aluminum Lake.

Evaluation:

Item	Comments on the Information Provided in NDA
Proprietary name and established name	**Satisfactory**
Dosage form and route of administration	tablet; orally Satisfactory
Active moiety expression of strength with equivalence statement (if applicable)	**N/A**
Inactive ingredient information (quantitative, if injectables 21CFR201.100(b)(5)(iii)).	Satisfactory ([redacted] (b) (4) is listed as its individual USP components)
Statement of being sterile (if applicable)	N/A
Pharmacological/ therapeutic class	Not Satisfactory
Chemical name, structural formula, molecular weight	Satisfactory
If radioactive, statement of important nuclear characteristics.	N/A
Other important chemical or physical properties (such as pKa or pH)	Satisfactory

[redacted] (b) (4)

(communicated to Applicant during Labeling negotiations)

#16. How Supplied/Storage and Handling Section

Reference ID: 3781820

Tablets

[redacted] (b) (4) Each white to off white, circular, biconvex, bevel-edged film coated, TILTAB tablet [redacted] (b) (4) debossed with "ap" and "550" and contains 200 mg of albendazole. [redacted] (b) (4)

Bottles of 2 Tablets NDC 52054-550-22
Bottles of 28 Tablets NDC 52054-550-28

Chewable Tablets

Each round, mottled pink, concave chewable tablet is debossed with "ap" above "551" and contains 200 mg of albendazole.

2 Tablets in 1 Blister Pack (configured as a Wallet Card) NDC 52054-551-22
6 Tablets in 1 Blister Pack; 2 Blister Packs in 1 Carton NDC 52054-551-12

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Item	Comments on the Information Provided in NDA
Strength of dosage form	Satisfactory
Available units (e.g., bottles of 100 tablets)	Satisfactory
Identification of dosage forms, e.g., shape, color, coating, scoring, imprinting, NDC number	Satisfactory
Special handling (e.g., protect from light)	Satisfactory
Storage conditions	Satisfactory

The Storage and Handling section is **Satisfactory**.

2. Immediate container label

The drug product is intended to be packaged in 6 count blister cards or 2 count wallet packs as seen below:

[redacted] (b) (4)

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(b) (4)

[redacted]

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(b) (4)

[redacted]

3. Carton Label

The blister cards will be packaged as a 12 count carton (two blister cards per carton).

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(b) (4)

[redacted]

Evaluation:

Item	Comments on the Information Provided in NDA
Proprietary name, established name (font size and prominence (FD&C Act 502(e)(1)(A)(i), FD&C Act 502(e)(1)(B), 21 CFR 201.10(g)(2))	Satisfactory
Dosage strength (21CFR 201.10(d)(1); 21.CFR 201.100(b)(4))	Satisfactory
Net quantity of dosage form (21 CFR 201.51(a))	Satisfactory
"Rx only" displayed prominently on the main panel (21 CFR 201.100 (b)(1))	Satisfactory
Expiration date and lot number (21 CFR 201.17 and 21 CFR 201.18)	Satisfactory

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Storage conditions	Satisfactory
Bar code (21CFR 201.25)	Satisfactory
NDC number (21 CFR 201.2; 21 CFR 207.35(b)(3)(i))	Satisfactory
Manufacturer/distributor's name 21CFR201.1(a)	Satisfactory
The list of inactive ingredients, 21CFR 201.10(a), if not oral dosage form; and quantitative ingredient information, if parenteral injection. 21CFR 201.100(b)(5)(iii)	Oral dosage form, no ingredient list necessary; Satisfactory
Statement of being sterile (if applicable)	N/A
"See package insert for dosage information" (21 CFR 201.55)	Satisfactory
"Keep out of reach of children" (Required for OTC but Optional for Rx drugs)	Satisfactory
Route of Administration (21 CFR 201.100(b)	Satisfactory Oral use therefore exempt from 201.100
Other	**N/A**

The carton label is satisfactory.

B. Environmental Assessment Or Claim Of Categorical Exclusion

Amedra claims categorical exclusion in compliance with 21 CFR 25.31 (a). The 200 mg Albenza Chewable Tablet, will not increase the use of the active moiety albendazole as this is a new dosage form that will substitute directly for the reference NDA's current approved formulation (NDA 20666). Categorical exclusion is granted.

III. List Of Deficiencies Communicated during review Cycle

Information Request 22-DEC-2014

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Chemistry Assessment Section

1. [redacted] (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:

   - [redacted] (b) (4)

4. Provide updated stability data for primary and supportive stability batches.

All items were resolved in review cycle. Application recommended for approval from CMC perspective.

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Appendix 1 – EES Report

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application:	NDA 207844/000	**Action Goal:**	
Stamp Date:	19-JUN-2014	**District Goal:**	18-FEB-2015
Regulatory:	11-JUN-2015		
Applicant:	AMEDRA PHARMS LLC 2 WALNUT GROVE DR STE 190 HORSHAM, PA 190447707	**Brand Name:** **Estab. Name:** **Generic Name:**	ALBENZA (ALBENDAZOLE)
Priority:	3	**Product Number; Dosage Form; Ingredient; Strengths**	
Org. Code:	520	001; TABLET, CHEWABLE; ALBENDAZOLE; 200MG	

Application Comment:

FDA Contacts:	C. STRASINGER	Prod Qual Reviewer	(HFD-800)	3017963776
	E. PFEILER	Micro Reviewer	(HF-22)	3017960642
	N. BHANDARI	Product Quality PM		2404023815
	G. DIBERNARDO	Regulatory Project Mgr	(HFD-520)	3017964063

Overall Recommendation:	ACCEPTABLE	on 26-AUG-2014	by R. XU	()	3017966187
	PENDING	on 16-JUL-2014	by EES_PROD		

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: CFN: (b) (4) FEI: (b) (4) (b) (4)

DMF No: **AADA:** (

Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Establishment Comment MANUFACTURE, PACKAGING, RELEASE TESTING, AND STABILITY TESTING OF THE CHEWABLE DRUG PRODUCT. (b) (4)

Profile: TABLETS, PROMPT RELEASE **OAI Status:** NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment					
OAI Submit To OC					
Request to Extend Re-eval Date To					
Extension Request Comment					
Reason					
SUBMITTED TO OC	16-JUL-2014				BHANDARIN
SUBMITTED TO DO	(b) (4)	10-Day Letter			SAFAAUAZIR
FDF - PDUFA GOAL DATE: 19-APR-2015					
DO RECOMMENDATION	21-JUL-2014			ACCEPTABLE	WALTERSJ

PREVIOUS INSPECTION OF THE FIRM WAS CONDUCTED FROM (b) (4) THE INSPECTION WAS A PRE-APPROVAL PRODUCT SPECIFIC INSPECTION. THIS INSPECTION DID RESULT IN THE ISSUANCE OF A FORM FDA-483, AND WAS CLASSIFIED VOLUNTARY ACTION INDICATED (VAI). THE INSPECTIONAL OBSERVATION WAS ISSUED DUE TO EMPLOYEES BEING ENGAGED IN THE PROCESSING OF A DRUG PRODUCT, AND LACKING THE TRAINING REQUIRED TO PERFORM SUCH FUNCTIONS. THE COVERED PROFILE CLASS WAS (b) (4)

THE MOST RECENT COMPREHENSIVE INSPECTION OF THE FIRM WAS CONDUCTED FROM (b) (4) SYSTEMS COVERED DURING THIS INSPECTION INCLUDED QUALITY, LABORATORY CONTROL, AND PRODUCTION. NO FDA-483 WAS ISSUED TO FIRM MANAGEMENT AT THE CONCLUSION OF THE INSPECTION. THE PROFILE CLASSES TCM AND TTR WERE FOUND ACCEPTABLE. THE INSPECTION WAS CLASSIFIED NO ACTION INDICATED (NAI) AS NO SIGNIFICANT DEFICIENCIES WERE OBSERVED. HOWEVER, DISCUSSION ITEMS ADDRESSED WITH FIRM MANAGEMENT ARE DESCRIBED BELOW:

-PROCESS VALIDATION OF (b) (4) WAS COMPLETED USING THREE BATCHES, WITHOUT JUSTIFICATION AS TO WHY ONLY THREE BATCHES WERE USED. (b) (4)

-THE FIRM'S BATCH RECORDS CONTAIN A SECTION FOR THE INDIVIDUAL PERFORMING AND CHECKING TO INITIAL, BUT ONLY ONE SPACE FOR THE DATE. DURING REVIEW OF BATCH RECORDS, THE CSO NOTICED INCONSISTENCY IN WHICH INDIVIDUAL (PERFORMER OR CHECKER) FILLED OUT THE DATE. ALSO, CORRECTIONS TO VERIFIED STEPS WERE NOT VERIFIED BY A SECOND INDIVIDUAL.

BASED UPON FILE REVIEW, THE DISTRICT RECOMMENDS APPROVAL OF THE FIRM FOR ITS LISTED RESPONSIBILITIES IN THE APPLICATION.

OC RECOMMENDATION	21-JUL-2014			ACCEPTABLE	SHARPT

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)

DMF No: **AADA:**

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Establishment Comment: API MANUFACTURER; ALBENDAZOLE, USP (on (b) (4)

Profile: (b) (4) **OAI Status:** NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment					
OAI Submit To OC					
Request to Extend Re-eval Date To					
Extension Request Comment					
Reason					
SUBMITTED TO OC	16-JUL-2014				BHANDARIN
OC RECOMMENDATION	26-AUG-2014			ACCEPTABLE	RHX

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