Finnish Medicines Agency

CERTIFICATE NUMBER: ***FIMEA/2023/005665***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Finland confirms the following:
The manufacturer: ***Nanjing King-Friend Biochemical Pharmaceutical Co. Ltd.***
Site address: ***No 16 Xuefu Road, Nanjing High and New Technology Development Zone, Nanjing, 210061, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100021124*** / ***LOC-100054143***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-01-18***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.6 Human or animal extracted products
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
Workshop 1	**-**	***Vial line 1***	**-**	***confidential***
Workshop 1	**-**	***Prefilled Syringe line 2***	**-**	***confidential***
Workshop 1	**-**	***Vial line 3***	**-**	***confidential***
Workshop 2	**-**	***Cartridge line 7***	**-**	***confidential***
Workshop 2	**-**	***Vial line 9***	**-**	***confidential***

2024-02-16

Name and signature of the authorised person of the Competent Authority of

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Confidential
Finnish Medicines Agency
Tel:***Confidential***
Fax:***Confidential***

12/29/2023
CEO YongQun Tang
Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (FDF Site)
Nanjing High And New No. 16 Xuefu Road; Technology Development Zone Nanjing, Jiangsu

Dear CEO YongQun Tang :

The U.S. Food and Drug Administration (FDA) conducted an inspection at Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd. (FDF Site), FEI 3010625707, located at Nanjing High And New, No. 16 Xuefu Road; Technology Development Zone, Nanjing, Jiangsu, from 10/30/2023 to 11/10/2023. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA’s assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER’s Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Melissa Y Giorgi via telephone at 19496084454 or email at Melissa.Giorgi@FDA.HHS.GOV.

Sincerely,

Melissa Y Giorgi
PROGRAM SUPPORT SPECIALIST
PHARMACEUTICAL QUALITY IV INVESTIGATION BRANCH (PHRM4-IB)

09/28/2024
President Chuan Qin
Kindos Pharmaceuticals Co., Ltd.
Chengdu Hi-Tech Comprehensive No. 8-9 Kexin Road;
Chengdu, Sichuan, 611731 China

Dear President Chuan Qin:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Kindos Pharmaceuticals Co., Ltd., FEI 3008865184, located at Chengdu Hi-Tech Comprehensive, No. 8-9 Kexin Road; Chengdu, Sichuan, 611731 China from 07/11/2024 to 07/19/2024. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI"). Based on this inspection, this facility is considered to be in a minimally acceptable state of compliance with regards to current good manufacturing practice (CGMP).

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA’s assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER’s Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA in accordance with the Freedom of Information Act (FOIA) and 21 CFR part 20. This, however, does not preclude you from requesting additional information under FOIA.

If you have any questions regarding this letter, you may contact Atul J. Agrawal or Rita K. Vick via email at Atul.Agrawal@FDA.HHS.GOV or Rita.Vick@FDA.HHS.GOV, respectively.

Sincerely,
Atul J. Agrawal
DIVISION DIRECTOR
DIVISION OF FOREIGN PHARMACEUTICAL QUALITY INSPECTION (DFPQI)

ANDA 205030

ANDA APPROVAL

Meitheal Pharmaceuticals, Inc.
U.S. Agent for Hong Kong King-Friend Industrial Company, Limited
2340 S. River Road, Suite 208
Des Plaines, IL 60018
Attention: Jay Catayong
Director, Regulatory Affairs

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on December 24, 2012, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Bleomycin for Injection USP, 15 units per vial and 30 units per vial.[1]

Reference is also made to the complete response letter issued by this office on April 4, 2016, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Bleomycin for Injection USP, 15 units per vial and 30 units per vial to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Blenoxane for Injection, 15 units per vial and 30 units per vial, of Bristol-Myers Squibb Company (BMS).

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANDA 075259/S-036

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Meitheal Pharmaceuticals Inc.
Attention: Roopang Shah, Director, Regulatory Affairs
8700 W Bryn Mawr Avenue, Suite 600S
Chicago, IL 60631

Dear Sir:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on March 22, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Dacarbazine for Injection USP, 200 mg/vial and 500 mg/vial.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Changes Being Effected in 30 Days," provides for drug product manufacturing site transfer to Kindos Pharmaceuticals Co., Ltd (Kindos) (FEI #3008865184) for 200 mg/vial strength only.

We have completed the review of this sANDA, as amended, and it is **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP’s website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer

you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Kimberly Hudgens, Regulatory Business Process Manager, at (240) 402 - 4884 or kimberly.hudgens@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:

Ee-Sunn (Joanne) Chia, Ph.D.
Director
Division of Product Quality Assessment X
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Niles Ron

Digitally signed by Niles Ron
Date: 5/29/2024 07:45:22PM
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ANDA 216590

ANDA APPROVAL

Meitheal Pharmaceuticals, Inc.
U.S. Agent for Kindos Pharmaceuticals Co., Ltd.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631
Attention: Roopang Shah
Associate Director, Regulatory Affairs

Dear Roopang Shah:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 2, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Leucovorin Calcium for Injection USP, 50 mg/vial, 100 mg/vial, 200 mg/vial, 350 mg/vial and 500 mg/vial, Single-Dose Vials.[1]

Reference is also made to the complete response letter issued by this office on December 27, 2022, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Leucovorin Calcium for Injection USP, 50 mg/vial, 100 mg/vial, and 350 mg/vial, Single-Dose Vials to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Leucovorin Calcium for Injection, 50 mg/vial, 100 mg/vial, and 350 mg/vial, of Hospira, Inc. (Hospira). Your Leucovorin Calcium for Injection USP, 200 mg/vial and 500 mg/vial, Single-Dose Vials can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third

parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] We note that the RLD upon which you have based this ANDA, Hospira's Leucovorin Calcium for Injection, 50 mg/vial, 100 mg/vial, and 350 mg/vial, are no longer being marketed in the United States and are currently listed in the discontinued section of FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Hospira's Leucovorin Calcium for Injection, 50 mg/vial, 100 mg/vial, and 350 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (81 FR 26800; May 4, 2016). This determination allows the Agency to approve ANDAs for the discontinued drug products.

Catherine Poole

Digitally signed by Catherine Poole
Date: 7/19/2023 11:51:30AM
GUID: 5407887a000a1c0c26055eafb8e3258a

ANDA 077356/S-033

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Meitheal Pharmaceuticals Inc.
8700 W Bryn Mawr Avenue
Ste 600S
Chicago, IL 60631

Attention: Christina Cutler
Manager, Regulatory Affairs

Dear Christina Cutler:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on October 31, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mitoxantrone Injection USP, 20 mg/10 mL, 25 mg/12.5 mL and 30 mg/15 mL (MDV).

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Prior Approval Supplement," provides for:

> Change in the sterile manufacturing site for the Mitoxantrone Injection, USP, 20 mg/10 mL and 25 mg/12.5 mL, MDV, from Teva Parenteral Medicines, Inc. (Teva) to Kindos Pharmaceuticals Co., Ltd. (Kindos; FEI #3008865184).

We have completed the review of this sANDA, as amended, and it is **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP’s website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Sara Harris, Regulatory Business Process Manager, at (301) 796 - 6748 or sara.harris@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:
Hasmukh Patel, Ph.D.
Director
Division of Product Quality Assessment III
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Aijin Shen

Digitally signed by Aijin Shen
Date: 4/25/2025 06:49:29AM
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ANDA 205696

ANDA APPROVAL

Meitheal Pharmaceuticals, Inc.
U.S. Agent for Hong King-Friend Industrial Company Limited
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631
Attention: Jay Catayong
Director, Regulatory Affairs

Dear Sir:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 19, 2013, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Cytarabine Injection, 2 grams/20 mL (100 mg/mL) Single-dose Vial.[1]

Reference is also made to the complete response letter issued by this office on November 30, 2016, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is **approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Cytarabine Injection, 2 grams/20 mL (100 mg/mL) Single-dose Vial can be expected to have the same therapeutic effect as that of the listed drug product upon which the agency relied as the basis of safety and effectiveness.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling materials prior to publication or dissemination. Please note that these submissions are voluntary. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert (PI), Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

You must also submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[2] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1st of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017, ANDAs must be submitted in eCTD format and beginning May 5, 2018, drug master files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

Sincerely yours,

{See appended electronic signature page}

For Vincent Sansone, PharmD
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, Teva Pharmaceuticals USA, Inc.'s (Teva's) Cytarabine for Injection USP, 2 grams/vial is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"). The Agency has determined that Teva's Cytarabine for Injection USP, 2 grams/vial, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (81 FR 3430; January 21, 2016). This determination allows the Agency to approve ANDAs for the discontinued drug product.

[2] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

Priya Shah

Digitally signed by Priya Shah
Date: 7/17/2018 09:47:45PM
GUID: 5256c7080002b0e78814870319c70608

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home | Back to Search Results

Product Details for ANDA 216355

PACLITAXEL (PACLITAXEL)
100MG/VIAL
Marketing Status: Prescription

Active Ingredient: PACLITAXEL
Proprietary Name: PACLITAXEL
Dosage Form; Route of Administration: POWDER; INTRAVENOUS
Strength: 100MG/VIAL
Reference Listed Drug: No
Reference Standard: No
TE Code: AB
Application Number: A216355
Product Number: 001
Approval Date: May 15, 2025
Applicant Holder Full Name: HAINAN SHUANGCHENG PHARMACEUTICALS CO LTD
Marketing Status: Prescription
Product Detail
Patent and Exclusivity Information