May 27, 2020

To,
Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned ('petitioner') submits this Citizen Petition electronically under Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 10.25(a), 10.30 and 314.93, to request the Food and Drug Administration to **designate a suitable alternative reference standard (RS)** for purpose of conducting *in vivo* bioequivalence studies to support our ANDA application for Dicloxacillin Sodium Capsules USP 125 mg, 250 mg and 500 mg with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

The request is being made on the following grounds;

1. The current Orange Book lists "Dicloxacillin Sodium Capsules (ANDA # 061454) EQ 500 mg of Sandoz Inc.", as Reference Standard (RS). However, though not listed as discontinued in electronic Orange Book, as per IMS (MAT) data quantity of the current reference standard is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for *in vivo* bioequivalence testing. Please also note that as per the record for application number (061454) in the National Drug Code directory, NDC package code (67296-1205-4) [Source NDC code: 0781-2258] is available. The non-availability statement of samples from the distributor indicate that the current designated reference standard samples are unavailable.

2. Approved generic product, "Dicloxacillin Sodium Capsules (ANDA # 062286) of Teva Pharmaceuticals USA Inc." listed in the Orange Book, is currently the highest marketed drug product and hence, eligible to be designated as Reference Standard due to limited or non-availability of the current Orange Book listed reference standard "Dicloxacillin Sodium Capsules (ANDA # 061454) EQ 500 mg of Sandoz Inc.",

A. Action Requested

Aurobindo Pharma Limited requests the Food and Drug Administration (FDA) to designate the approved "Dicloxacillin Sodium Capsules 500 mg (ANDA # 062286) of Teva Pharmaceuticals USA Inc." as a new Reference Standard, upon which ANDA applicant can rely for purpose of *in vivo* bioequivalence testing required for ANDA filing.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (The Orange Book).

FDC Act §505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA. To obtain ANDA approval, the application sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, has essentially identical labeling.

Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) database current through May 2020* is provided in following table;

Market Status	**RX**	**RX**
Active Ingredient	Dicloxacillin Sodium	Dicloxacillin Sodium
Proprietary Name	Dicloxacillin Sodium	Dicloxacillin Sodium
Application No.	**A061454**	**A062286**
Product Number	003	002
Dosage Form / Route	Capsule; Oral	Capsule; Oral
Strength	EQ 500MG BASE	EQ 500MG BASE
TE Code	AB	AB
RLD	**No**	No
RS	**RS**	No
Applicant Holder	Sandoz Inc.	Teva Pharmaceuticals USA Inc.
Approval Date	Prior to Jan 1, 1982	Jun 3, 1982

* Data accessed on May 27, 2020.

Other approved NDA/ANDAs (# N050011, A060254 and A062238) of Dicloxacillin Sodium Capsules are listed in the discontinued section of the orange Book and currently there is no RLD available for this drug product in Orange Book.

Due to market unavailability of designated reference standard in sufficient quantity, evaluation/comparison of Aurobindo's generic drug could not be executed.

As per Draft Guidance for Industry, ***Referencing Approved Drug Products in ANDA Submissions, Ill.* C.2 *and* 3**,

"FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold."

"If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

The Petitioner (Aurobindo Pharma Limited) therefore requests FDA to designate one of the approved generic products and preferably "Dicloxacillin Sodium Capsules 500 mg (ANDA # 062286) of Teva Pharmaceuticals USA Inc." as a new Reference Standard (RS) considering it appears to lead the U.S. market in terms of number of capsules sold (as per IMS data) and should therefore be more readily accessible and more appropriate for RS designation..

In support of the designation of the reference standard to Approved Generic Product "Dicloxacillin Sodium Capsules 500 mg (ANDA # 062286) of Teva Pharmaceuticals USA Inc.", we have included the following data:

1. Current Orange Book Search Results
2. NDC Directory Search Results
3. Drugs@FDA Search Results
4. Detailed IMS, Moving Annual Total (MAT) data indicating Approved Generic product "Dicloxacillin Sodium Capsules (ANDA # 062286) of Teva Pharmaceuticals USA Inc.", as the leading player in the U.S market.
5. Non availability of samples statement from pharmacy/distributor.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31(a) and 25.15(d).

D. Economic Impact Statement

Pursuant to 21 C.F.R. 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. This information will be promptly provided, if so requested.

E. Certification

The undersigned (petitioner) certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to this petition.

Sincerely yours,

Blessy Johns

Digitally signed by Blessy Johns
DN: c=US, st=New Jersey, l=Dayton, o=Aurobindo Pharma USA, Inc., cn=Blessy Johns, email=bjohns@aurobindousa.com
Date: 2020.05.27 12:59:14 -04'00'

Blessy Johns
US Agent for Aurobindo Pharma Limited

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Mkt.Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A061454	CAPSULE	ORAL	EQ 125MG BASE				SANDOZ INC
RX	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A061454	CAPSULE	ORAL	EQ 250MG BASE	AB			SANDOZ INC
RX	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A062286	CAPSULE	ORAL	EQ 250MG BASE	AB			TEVA PHARMACEUTICALS USA INC
RX	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A061454	CAPSULE	ORAL	EQ 500MG BASE	AB		RS	SANDOZ INC
RX	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A062286	CAPSULE	ORAL	EQ 500MG BASE	AB			TEVA PHARMACEUTICALS USA INC
DISCN	DICLOXACILLIN SODIUM	DYCILL	A060254	CAPSULE	ORAL	EQ 250MG BASE				GLAXOSMITHKLINE
DISCN	DICLOXACILLIN SODIUM	DYCILL	A062238	CAPSULE	ORAL	EQ 250MG BASE				GLAXOSMITHKLINE
DISCN	DICLOXACILLIN SODIUM	DYCILL	A060254	CAPSULE	ORAL	EQ 500MG BASE				GLAXOSMITHKLINE
DISCN	DICLOXACILLIN SODIUM	DYCILL	A062238	CAPSULE	ORAL	EQ 500MG BASE				GLAXOSMITHKLINE
DISCN	DICLOXACILLIN SODIUM	PATHOCIL	N050011	CAPSULE	ORAL	EQ 250MG BASE				WYETH AYERST LABORATORIES
DISCN	DICLOXACILLIN SODIUM	PATHOCIL	N050011	CAPSULE	ORAL	EQ 500MG BASE				WYETH AYERST LABORATORIES
DISCN	DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	A061455	FOR SUSPENSION	ORAL	EQ 62.5MG BASE/5ML				APOTHECON INC DIV BRISTOL MYERS SQUIBB
DISCN	DICLOXACILLIN SODIUM	DYNAPEN	N050337	FOR SUSPENSION	ORAL	EQ 62.5MG BASE/5ML				APOTHECON INC DIV BRISTOL MYERS SQUIBB
DISCN	DICLOXACILLIN SODIUM	PATHOCIL	N050092	FOR SUSPENSION	ORAL	EQ 62.5MG BASE/5ML				WYETH AYERST LABORATORIES

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PIN IT (HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

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Search Results: *'061454'*

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Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
Dicloxacillin Sodium	67296-1205-4	500 mg/1	CAPSULE	ORAL	ANDA061454	RedPharm Drug, Inc.	67296-1205	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/1971	N/A
Dicloxacillin Sodium	63629-1350-1	250 mg/1	CAPSULE	ORAL	ANDA061454	Bryant Ranch Prepack	63629-1350	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/1971	N/A
Dicloxacillin Sodium	63629-1350-2	250 mg/1	CAPSULE	ORAL	ANDA061454	Bryant Ranch Prepack	63629-1350	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/1971	N/A
Dicloxacillin Sodium	63629-1350-3	250 mg/1	CAPSULE	ORAL	ANDA061454	Bryant Ranch Prepack	63629-1350	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	04/01/1971	N/A

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Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

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Search Results: *'062286'*

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Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
Dicloxacillin Sodium	50090-0310-0	500 mg/1	CAPSULE	ORAL	ANDA062286	A-S Medication Solutions	50090-0310	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	55289-592-40	250 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	55289-592	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	43063-473-20	500 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	43063-473	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	50090-0310-4	500 mg/1	CAPSULE	ORAL	ANDA062286	A-S Medication Solutions	50090-0310	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	0093-3123-01	250 mg/1	CAPSULE	ORAL	ANDA062286	Teva Pharmaceuticals USA, Inc.	0093-3123	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	0093-3125-01	500 mg/1	CAPSULE	ORAL	ANDA062286	Teva Pharmaceuticals USA, Inc.	0093-3125	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	50090-0310-1	500 mg/1	CAPSULE	ORAL	ANDA062286	A-S Medication Solutions	50090-0310	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	55289-592-10	250 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	55289-592	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	55289-592-20	250 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	55289-592	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	43063-180-06	250 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	43063-180	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	55289-592-28	250 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	55289-592	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	43063-473-30	500 mg/1	CAPSULE	ORAL	ANDA062286	PD-Rx Pharmaceuticals, Inc.	43063-473	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A
Dicloxacillin Sodium	66267-073-28	500 mg/1	CAPSULE	ORAL	ANDA062286	NuCare Pharmaceticals, Inc.	66267-073	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
Dicloxacillin Sodium	66267-073-30	500 mg/1	CAPSULE	ORAL	ANDA062286	NuCare Pharmaceticals, Inc.	66267-073	Dicloxacillin Sodium	DICLOXACILLIN SODIUM	HUMAN PRESCRIPTION DRUG	09/30/1990	N/A

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National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Drugs@FDA: FDA-Approved Drugs

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD	TE Code	Application No.	Company
DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	EQ 500MG BASE	CAPSULE;ORAL	Prescription	No	AB	061454	SANDOZ
DICLOXACILLIN SODIUM	DICLOXACILLIN SODIUM	EQ 500MG BASE	CAPSULE;ORAL	Prescription	No	AB	062286	TEVA