

K.A.
Shri Harish Reddy
ADC



भारत सरकार/GOVERNMENT OF INDIA,
वाणिज्य एवं उद्योग मंत्रालय/ MINISTRY OF COMMERCE & INDUSTRY
विकास आयुक्त का कार्यालय/ OFFICE OF THE DEVELOPMENT COMMISSIONER,
सीपज विशेष आर्थिक क्षेत्र / SEEPZ - SPECIAL ECONOMIC ZONE
Pune Office: SEZ Bhavan, Plot No. 6/1, MIDC, Phase-III, Hinjewadi, Pune -
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SEEPZ-SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08/VOL-V 1354. 223968 BY REGISTERED A.D. 02/08/2023	
ORDER-IN-ORIGINAL	Date of Order: 30-06-2023 Date of Issue: 04-09-2023.
Passed by :	Shyam Jagannathan, IAS Development Commissioner, SEEPZ-SEZ
In the Matter of:	M/s. Wockhardt Ltd., Plot E-1/1 in Wockhardt Infrastructure Development Ltd.-SEZ, MIDC Shendra, Aurangabad, Maharashtra 431201 Show Cause Notice No. - i) SEEPZ-SEZ/NEWSEZ/WOCKDT/ AURBD/MTRG/01/ 2013-14/15848 dated 03-08-2017 and CORRIGENDUM TO SHOW CAUSE NOTICE NO. SEEPZ-SEZ/NEW-SEZ/WOCKHDT-AURBD/01/07-08/VOL-V dated 01.12.2022 ii) SEEPZ-SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08/VOL-V dated 30.11.2022

- 1 यह प्रति उपयोग के लिए उस व्यक्ति को नि:शुल्क प्रदान की जाती है, जिस को यह आदेश जारी किया गया है ।
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- 2 इस आदेश के विरुद्ध अपील दाखिल की जा सकती है । इस आदेश से व्यथित कोई/ पार्टी विदेश व्यापार (विकास तथा विरुद्ध) (अधिनियम १९९२, की धरा -१५ के अधीन उपर्युक्त प्राधिकारी अर्थात अपीली समिति, वाणिज्य तथा उद्योग मंत्रालय, वाणिज्य विभाग, उद्योग भवन, नई दिल्ली -११०१०७ के समक्ष इस आदेश की प्रतिलिपि के साथ न्याय निर्णय आदेश के तामिल किए जाने की तारीख से ४५ दिनों अंदर अपील के समर्थन में अपील के अनुलग्नक के रूप में साक्ष्यों की प्रतिलिपियों के साथ जिन पर अपील का आधार बनता हो, अपील दाखिल कर सकती है ।
An appeal against this order lies, any person/party aggrieved by this order may under section 15 of Foreign Trade (Development & Regulation) Act 1992, file an appeal before the appropriate authority i.e., appellate committee cell, Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Udyog Bhawan, New Delhi-110107 within 45 days from the date of service of the adjudication order together with a copy of this order and as complete set of evidence in the form of annexure to the appeal relied upon in support of the appeal.
- 3 यदि आप इस आदेश के विरुद्ध अपील दाखिल करते हो, तो कृपया विकास आयुक्त कार्यालय, सीपज, अंधेरी (पु), मुंबई-९६ को अपील संख्या तथा तारीख की सूचना दे ।
If you file an appeal against this order, please intimate the appeal no. and date to the Officer of the Development Commissioner, SEEPZ, Andheri (E), Mumbai-96.

13/8/23

BRIEF FACTS OF THE CASE

1. WHEREAS, M/s. Wockhardt Ltd, (hereinafter referred as 'the unit') having IEC 0388084685, operational from premises situated at Plot E-1/1 in Wockhardt Infrastructure Development Ltd.-SEZ, MIDC Shendra, Aurangabad, Maharashtra 431201, are holders of Letter of Approval No. SEEPZ-SEZ / NEWSEZ / WOCKHARDT-AURBD/ 01 / 2007-08 dated 20.07.2007 issued by the Development Commissioner, SEEPZ-SEZ to undertake authorized operation of pharmaceutical products for human consumption (tablets / capsules / vials). Whereas, as per the LOA granted to the Unit on inception and renewed from time to time, the Unit has all along held approval for undertaking authorized operations as export of pharmaceutical products for human consumption (tablets / capsules / vials) as stated above, subject to fulfillment of conditions in the LOAs issued to it from time to time.
2. WHEREAS, it appears that the unit has accepted the terms and conditions of the Letters of Approval issued to it including renewals/extensions thereof. The Unit has also executed Bond-Cum-Legal Undertaking with the Development Commissioner, SEEPZ-SEZ in terms of the LOAs granted to it from time to time. It further appears that as per record, the Unit has commenced commercial production w.e.f. 23.05.2012.
3. WHEREAS, it appears that for the purpose of renewal of LOA for the third block of five years from 23.05.2022 to 22.05.2027 certain information necessary for renewal was sought from the Unit. Based on the information provided by the Unit and verification submitted by the Specified Officer, Wockhardt Infrastructure Development Ltd.-SEZ, Aurangabad, it has been revealed that the Unit has achieved Negative NFE in 1st and 2nd Block as per details provided in Table-I herein under:

TABLE-I

BLOCK Period	Cumulative Net Foreign Exchange Earning (NFE) achieved figures are in (in Rs. Lacs)	Cumulative % NFE achieved
2012-13 to 2016-17 (First Block)	- 5280.55	- 35.13%
2017-18 to 2020-21 (Second Block)	- 5504.68	- 47.98%

- 4.1 WHEREAS, the performance of the unit for Block period i.e. FY 2012-13 to FY 2016-17 was earlier monitored by the Approval Committee in its meeting held on 29.06.2017. Whereas the Committee, upon, inter-alia, noted the achievement of the Unit recorded observation that the unit had achieved Negative NFE of Rs. (-)3707.98 Lakhs. Whereas, subsequent to issuance of SCN, it was observed that the figures reported in APR in hard copy were not matching with the figures reported in SEZ online. Accordingly, a detailed

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justification for the same was called for. Subsequently the unit filed revised APR for the period 2012-13. Since, the value of import of Raw material was shown wrongly. As per the Office File (Note dated 06.07.2018), it was proposed that since the figures reported in the APR which was placed before the UAC for monitoring purpose were wrong, the monitoring of performance for the period from 2012-13 to 2016-17 be once again placed before the UAC for monitoring purpose.

- 4.2 WHEREAS, the performance of the unit for two Block period i.e. FY 2012-13 to FY 2016-17 and FY 2017-18 to FY 2020-21 was again monitored by the Approval Committee in its meeting held on 26.07.2022. Whereas the Committee, upon, inter-alia, noted the achievement of the Unit recorded observation that the unit had achieved **Negative NFE of Rs. (-) 5,280.55 Lakhs** in first block period i.e., 2012-13 to FY 2016-17 on cumulative basis. The Committee has directed to issue necessary corrigendum to the above referred SCN to rectify the change in the negative NFE achieved by the Unit in the first block period.
- 4.3 WHEREAS, the Committee further monitored the performance of the Unit for the second block period i.e. from 2017-18 to 2020-21 and noted that in the second block period also the unit has achieved **Negative NFE of Rs. (-) 5,504.68 Lakhs on cumulative basis as on 31.03.2021**. The Committee has directed that action be initiated against the notice under Foreign Trade (Development & Regulation) Act, 1992 for non-achievement of positive NFE during the said block period.

RULE POSITION

- 5.1 The legal statutes relevant to the present proceedings are:
- i) The SEZ Act, 2005
 - ii) The SEZ Rules, 2006
 - iii) The Foreign Trade (Development & Regulation) Act, 1992 (The FTDR)
- Some of the specific provisions with particular relevance to the instant case are reproduced below:
- 5.2 According to the provisions of Section 2[c] of the SEZ Act, 2005, "Authorized operations" means operations which may be authorized under sub-section (2) of Section 4 and sub-section (9) of Section 15.
- 5.3 As per sub-section 9 of Section 15 which provides for setting up of Unit, The Development Commissioner may, after approval of the proposal referred to in sub-section (3), grant a letter of approval to the person concerned to set up a Unit and undertake such operations which the Development Commissioner may authorize and every such operation so Authorized shall be mentioned in the letter of approval.
- 5.4 As per Rule 19(6B) of the SEZ Rules, 2006
"The renewal of Letter of Approval shall be based on the evaluation of

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the following criteria namely: -

- (i)
- (ii)
- (iii)
- (iv)
- (v) **Undertaking of any activity not sanctioned or approved by the Development Commissioner."**

5.5 As per Rule 54(2) of the SEZ Rules, 2006

"(2) In Case the Approval Committee comes to the conclusion that a **Unit has not achieved positive Net Foreign Exchange Earning**, or stipulated Value Addition as specified in rule 53 or failed to abide by any of the term and conditions of the Letter of Approval or Bond-cum-Legal Undertaking, without prejudice to the action that may be taken under any other law for the time being in force, the said Unit shall be liable for penal action under the provisions of the Foreign Trade Development and Regulation) Act, 1992."

5.6 **Section 11(2) of the Foreign Trade Development and Regulation Act, 1992 provides that** where any person makes or abets or attempts to make any export or import in contravention of any provision of this Act or any rules or orders made thereunder or the foreign trade policy, he shall be liable to a penalty not less than ten thousand rupees and not more than five times the value of the goods or services or technology in respect of which any contravention is made or attempted to be made, whichever is more."

6. It therefore appeared that **M/s. Wockhardt Ltd.** has violated the provisions of Rule 54(2) of the SEZ Rules, 2006 for not achieving positive Net Foreign Exchange Earning (NEF), thereby rendering themselves liable for penal action under Section 11(2) of the Foreign Trade (Development & Regulations) Act, 1992 in terms of provisions of Rule 54 (2) of the SEZ Rule, 2006.

7. Accordingly, the unit was issued Show Cause Notice bearing No. SEEPZ-SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08/Vol-V/1048 dated 30 November 2022 and Corrigendum to Show Cause Notice No SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08/Vol-V/1050 dated 01.12.2012, asking the unit to show cause as to why: -

- (i) action should not be initiated against the Unit for violation of condition (iii) of Letter of Approval SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08 dated 20.07.2007 and condition no. 8 of the Bond-cum-Legal undertaking executed on 26.09.2007 and 14.11.2014, 07.10.2020 and 02.11.2022.
- (ii) penalty should not be imposed upon them under Section 11(2) of the Foreign Trade (Development & Regulations) Act, 1992 read with Rule 80 and Rule 54 (2) of SEZ Rules, 2006.

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Unit's submission

8. The unit vide their letter dated 28.12.2022 has submitted their reply to the Show Cause Notice, wherein they submitted that:
- 8.1 They have done Expansion of Unit to include Liquid Oral Facility in the year 2013-14 which required importing machineries resulting into increase in import expenditure and negative NFE;
- 8.2 US FDA inspected the site and had given some observations which they had complied accordingly paid USFDA fee till 31.12.2022. They are still waiting the surprise inspection to happen anytime, which is beyond their control, which may result in increase in Export post approval after inspection;
- 8.3 They have also taken approval for manufacturing of Sputnik V vaccine from the Authority somewhere in May 2021 and accordingly they have procured RM/PM and machinery for the same. However, due to Geo-political situation arising pertaining to Russia-Ukraine war the project is on halt, which is again beyond their control;
- 8.4 further, due to global pandemic i.e. COVID-19 in the year 2020 all their export order got cancelled and there was restrictions on export;
- 8.5 Measures for achieving positive NFE;
- i) they have submitted broad-banding request for addition of 5 new products in LOA, which can increase their exports for the coming block;
 - ii) they are shifting some of their products from their EOU plant to SEZ Unit which are similar in formulation;
 - iii) apart from US and European Markets they are also trying for other countries regulatory approvals for which inspection are lined up in their facility;
 - iv) in view of the huge investment in their unit i.e. around Rs.600 crores which consist of more than Rs.200 crores of import of RM/PM and around Rs.400 crores of import of Capital Goods;
- 8.6 they have taken substantial steps towards achieving positive NFE; however, being a pharmaceutical company, they have to get product wise and facility approvals from the Regulatory and Statutory Authorities on regular basis for smooth operations.
- 8.7 they have done huge investment around Rs.600 crores, thereby resulting in Negative NFE;
- 8.8 they are diversifying their portfolio and new venturing into manufacturing of vaccines;
- 8.9 In view of above submission, the unit has requested that a lenient view may be taken by complete waiver of penalty or imposing a minimum penalty to meet the ends of justice and further prayed the following:

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- I) impugned SCN proposing to impose penalty be set aside.
 II) to grant such other relief/s as the authority may deem fit.

- 8.10** the major factor for not achieving positive NFE was due to Covid-19 global pandemic vis-à-vis USFDA not visiting their facility; the Unit tried to reduce cumulative Negative gap in first 2 years of second block; however due to covid-19 pandemic there were restrictions on cross border exports and many of their advance orders got cancelled in view of pandemic;
- 8.11** there are upcoming site inspections lined up in the coming years from respective countries, the same has been also highlighted in the UAC meeting dated 26.07.2022.
- 8.12** In view of the above submission, the unit has requested the Authority to kindly place their submission on records and consider this as their final reply towards issue of Show Cause Notice.

Record of Personal Hearing

- 9.** A Personal Hearing in the matter was held on 13.02.2023 at 16.30 hrs. The representatives of the unit reiterated their submission made in their written reply to the Show Cause Notice and requested for lenient view to be taken against them.

Observations and Findings

- 10.1** I have carefully gone through the Show Cause Notice, submission made by the unit in reply to the Show Cause Notice and oral submission made during Personal Hearing.
- 10.2** I find that the facts of the case as per the records are as under: -
- 10.3** The Unit is engaged in pharmaceutical products manufacturing activity and having unit in Wockhardt Infrastructure Development Ltd. SEZ, MIDC Aurangabad;
- 10.4** In terms of Rule 54 of the SEZ Rules, 2006, the Monitoring of Performance of the Unit was undertaken for two Block period i.e. FY 2012-13 to FY 2016-17 and FY 2017-18 to FY 2020-21 by the Unit Approval Committee in its meeting held on 26-07-2022. The Committee during the Monitoring observed that the Unit has not achieved positive NFE as detailed below totally amounting to Rs. - 10,785.23 Lakhs.

TABLE-I

Period	NFE Achieved in INR (in Lakhs)
2012-13 to 2016-17 (First Block)	- 5280.55
2017-18 to 2020-21 (Second Block)	- 5504.68

- 10.5 Section 2(z) of the SEZ Act, 2005 states that:**
 2(z) "Services" means such tradable services which -

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- (i) are covered under the General Agreement on Trade in Services annexed as IB to the Agreement establishing the World Trade Organisation concluded at Marrakesh on the 15th day of April 1994;
- (ii) may be prescribed by the Central Government for the purposes of this Act; and
- (iii) earn foreign exchange.'

- 10.6** I find that the Unit has violated the condition No (iii) of the Letter of Approval No. SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08 dated 20.07.2007 and condition no. 8 of the Bond-cum-Legal undertaking executed on 26.09.2007 and 14.11.2014, 07.10.2020 and 02.11.2022.
- 10.7** During the monitoring of performance of the unit it is observed that during the block period from 2012-13 to 2016-17 the unit has exported the products valued at Rs. 15,033.53 Lakhs and has achieved **negative NFE of Rs. (-) 5,280.55 Lakhs** which is **(-35.13%)**. For the block period 2017-18 to 2020-21 they have exported the products valued at Rs. 11,472.51 Lakhs and have achieved **negative NFE of Rs. (-)5,504.68 Lakhs** which is **(-47.98%)**.
- 10.8** One of the major criteria to be considered during the monitoring of performance of the unit is that the unit has to achieve positive Net Foreign Exchange. In this case I find that the unit has **not achieved the positive NFE** and the unit has adhered to all other compliances required as per the provisions of the Sections and Rules of SEZ except not achieving positive NFE.
- 10.9** The unit in their submissions has admitted that they have done expansion of the Unit to include Liquid Oral facility in the year 2013-14 which required importing machineries resulting into increase in import expenditure and negative NFE. Major factor for not achieving positive NFE was due to Covid 19 global pandemic, restriction of cross border, cancellation of advance orders and USFDA not visiting their facility.
- 10.10** I find that the Unit has taken measure steps for achieving positive NFE like broad banding of 5 new products, shifting of their products from EOU to SEZ Unit which can increase their exports in the coming block.
- 11.** In view of above discussion, I find that the unit has violated the provisions of Rules 19(6B) of the SEZ Rules, 2006 by not achieving positive NFE thereby rendering themselves liable for penal action under Section 11(2) of the Foreign Trade (Development & Regulations) Act, 1992 as provided for in Rule No 54 (2) of the SEZ Rules, 2006.
- 12.** In view of the above-mentioned facts and circumstances, taking a lenient view based on the fact that there was no malafide intention on the part of the unit to contravene any of the provisions of the Special Economic Zones Act, 2005 and Rules there under, I pass the following order: -

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ORDER

13. I impose a penalty of Rs.1,07,85,000/- (Rupees One Crore Seven Lakh Eighty Five Thousand only) on **M/s. Wockhardt Ltd** having Letter of Approval No. SEZ /NEWSEZ /WOCKDT -AURBD/01/07-08 dated 20.07.2007 renewed from time to time for violation of **Rule 19 (6B) under the provisions of Section 11(2) of the Foreign Trade (Development and Regulation) Act, 1992** as provided for in Rule 54 (2) of SEZ Rules, 2006. The same may be paid forthwith.
14. This action is taken without prejudice to any other action that may be taken against **M/s. Wockhardt Ltd.** under the SEZ Act, 2005, SEZ Rules, 2006 and FT (D&R) Act, 1992 or any other law for the time being in force.



(Shyam Jagannathan, IAS)
Development Commissioner
SEEPZ-SEZ

No. SEEPZ-SEZ/NEWSEZ/WOCKDT-AURBD/01/07-08/VOL-V
Date:

To,
M/s. Wockhardt Ltd.,
Plot E-1/1 in Wockhardt Infrastructure Development Ltd.-SEZ,
MIDC Shendra, Aurangabad, Maharashtra 431201

Copy to:

1. The Joint Development Commissioner, SEZ-Pune Cluster
3. The Specified Officer, Wockhardt Infrastructure Development Ltd.-SEZ.
4. SEEPZ-SEZ (IT Cell) with Directions for uploading the order in DGFT website.
5. OIO-Master File