



Director General SEZEP <dg@sezepc.in>

REQUESTING CLARIFICATION REGARDING AFFIXING OF LABELS ON EMPTY CONTAINERS, SUPPLIED BY ANOTHER FDA LICENSED UNIT WITHIN SEZ (DUTY FREE - BONDED AREA)

24 messages

Vivek - Milaks <vivek@milaks.com>

18 June 2026 at 14:45

To: "comfdca@gujarat.gov.in." <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>

18th June, 2026**URGENT MATTER / REGISTERED A.D.**

The Joint Commissioner (Drugs),
Food & Drugs Control Administration,
Gujarat State, Dr. Jivraj Mehta Bhavan,
Block no. 8, 1st Floor,
Gandhinagar – Gujarat.

Respected Sir,

Sub. # REQUESTING CLARIFICATION REGARDING AFFIXING OF LABELS ON EMPTY CONTAINERS, SUPPLIED BY ANOTHER FDA LICENSED UNIT WITHIN SEZ (DUTY FREE - BONDED AREA)

This has reference to our rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave) and duly approved through by Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.

As we have being receiving prospective requirement from our customers to provide them with labelled rigid bottles/jars; we hereby respectfully seek clarification under the provision of the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 regarding the proposed activity to undertake affixing of labels on empty rigid bottle/jar and to supply the same to the said customer who as well is based in Kandla SEZ and who has been duly approved / licensed with your goodself for manufacture of cosmetic products.

For your kind reference, the brief description :

- We are a rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave under Ministry of Commerce & Industry) and making supplies of our packaging product to Export Oriented Units in SEZ's and approved through Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.
- Our client is a Cosmetic Manufacturing Unit and based in Kandla Special Economic Zone and duly registered under Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020. The said unit is engaged in manufacturing cosmetic products for export from India and aswell approved through Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone

- Our client has requested us to provide the empty rigid packaging material comprising bottles / jars duly affixed with product labels.
- The labels shall be provided to us by the client and printed with all essential details required by statute for the export products in overseas market as well as in compliance to Cosmetic Rules 2020 / Drugs and Cosmetic Act 1940.

The label shall bear :

- The product brand name;
- The product details;
- Cosmetic manufacturing license/neutral code details, etc.
- Any such declarations as approved and controlled by the buyer

Pertinent to state, the above details will be in compliance to the Cosmetic Rules 2020 / Drugs and Cosmetic Act 1940 as well as in compliance to the laws prevailing in overseas country where the product is required to be exported. The label affixing activity shall be carried out on Empty Rigid Bottle / Jars only and NOT on the finished product.

- **Our activity shall be restricted to affixing the labels as per the customer required on EMPTY RIGID BOTTLE / JAR.**
- **No Finished Cosmetic Product shall be supplied by the customer and that we shall NOT be doing any affixing of labels on the final / finished product.**

-

- We shall be maintaining proper records of the labels provided to us by our client and shall be returning back 100% of the quantity, including the rejects.
- For the said activity, all needed approvals have been already taken from the Office of The Development Commissioner, Kandla SEZ and the same forms a part of our authorized operation.

In view the above, we hereby seek your clarification as to –

- **Whether affixing labels, supplied by another licensed cosmetic manufacturer, on empty containers; without the presence, handling, filling, packing, repackaging, storage or manufacture of any cosmetic product, constitutes manufacturing of a cosmetic product under Section 3(f) of the Drugs and Cosmetic Act 1940**
- **Whether the said affixing of label on empty containers (supplied by another licensed cosmetic manufacturer) require any license, approval or endorsement under the Cosmetic Rules 2020.**

Requesting your kind and early clarification.

Thanking you in anticipation.

Yours sincerely,

For V. MILAK ENTERPRISES,

(VIVEK MILAK)

Parnter.

C.C. # The Drugs Controller General of India, CDSCO – New Delhi.

The Development Commissioner, Kandla SEZ.

Export Promotion Council for EOUs & SEZs (SEZEPC)

Confederation of Indian Industry

Indian Drug Manufacturers Association

Director General SEZEPC <dg@sezepc.in>
To: Vivek - Milaks <vivek@milaks.com>

18 June 2026 at 17:37

Has there been any objection to your activity by the office of the Drugs Controller General of India, CDSCO ?

Regards,

Alok Chaturvedi
DG,EPCES

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>
To: Director General SEZEPC <dg@sezepc.in>

18 June 2026 at 18:26

Dear Sir,

As discussed, basis the requirement we had approached the LOCAL FDA Office here in Kutch who inturn had made a visit to our unit and were objecting the activity with the remarks that we should take FDA Registration.

Although we had already represented to them :

- That we are NOT a cosmetic manufacturing unit and we are a rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave under Ministry of Commerce & Industry) and into manufacturing of packaging product to be sold to Export Oriented Units in SEZ's and approved through Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.
- That our client is also operating in Kandla SEZ as a Cosmetic Manufacturing Unit duly registered under Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020. The said unit is engaged in manufacturing cosmetic products for export from India and aswell approved through Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone

- Our client has requested us to provide the empty rigid packaging material comprising bottles / jars duly affixed with product labels.
- **Our activity shall be restricted to affixing the labels as per the customer required on EMPTY RIGID BOTTLE / JAR.**
- **No Finished Cosmetic Product shall be supplied by the customer and that we shall NOT be doing any affixing of labels on the final / finished product.**
- We shall be maintaining proper records of the labels provided to us by our client and shall be returning back 100% of the quantity, including the rejects.

Being only a packaging manufacturing unit only – undertaking labelling activity on empty jars/bottles and with NO handling of finished cosmetic product or repacking or storage; the Drugs and Cosmetic Act would not apply to us and not covered under the manufacturing definition of the Drugs & Cosmetic Act / Cosmetics Rules under Section 3(f).

With so be the status; we hereby request your kind support to get the clarification so that we can operate as an ancillary MSME unit and aswell be a part into export promotion from our country as an SEZ unit.

Thanks in anticipation.

With Warm Rgds.,
VIVEK MILAK

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

19 June 2026 at 12:32

To: "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "sechfwd@gujarat.gov.in" <sechfwd@gujarat.gov.in>, "dci@nic.in" <dci@nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, Director General SEZEPC <dg@sezepc.in>, EPCES <epces@epces.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

23 June 2026 at 14:03

To: "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "sechfwd@gujarat.gov.in" <sechfwd@gujarat.gov.in>, "dci@nic.in" <dci@nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, Director General SEZEPC <dg@sezepc.in>, EPCES <epces@epces.in>

R E S E N T > // URGENT MATTER

[Quoted text hidden]

Director General SEZEPC <dg@sezepc.in>

23 June 2026 at 14:48

To: dci@nic.in

Cc: secyhfw@nic.in

Dear Dr Raghuvanshi

Please refer to the trailing email from a rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave) which is duly approved by Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.

The unit wants to undertake affixing of labels on empty rigid bottle/jar and to supply the same to the a customer in Kandla SEZ only and which has been duly approved /

licensed by Drug Controller for manufacture of cosmetic products under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020.

The local Food and Drug Controller office visited them and asked them to obtain a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 even though they will be just affixing printed labels on empty rigid bottles/jars and supplying them to the their customer who already has license.

The unit manufactures no cosmetics.

It is requested that the case may kindly be examined and the local office may be advised not to insist on a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 as the unit is not manufacturing any cosmetics. The unit will just be affixing printed labels on empty rigid bottles/jars.

Regards

Alok Chaturvedi
DG, SEZEPC

Alok V Chaturvedi, IAS(Retd) | Director General,
Mobile +91 8130525959 | Tel: +91 11 23329770
Email : dg@epces.in
Export Promotion Council for EOUs and SEZs,
A101, 10th Floor Himalaya House 23, KG Marg, New Delhi, Delhi 110001

[Quoted text hidden]

Director General SEZEPC <dg@sezepc.in>
To: Vivek - Milaks <vivek@milaks.com>

23 June 2026 at 14:55

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>
To: Director General SEZEPC <dg@sezepc.in>

23 June 2026 at 16:54

Thanks for support Sir.

Appreciate all the effort to receive the clarification early so as to enable us to commence the activities.

With Warm Rgds.,
VIVEK MILAK

From: Director General SEZEPC <dg@sezepc.in>
Sent: 23 June 2026 14:55
To: Vivek - Milaks <vivek@milaks.com>

[Quoted text hidden]

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com> 26 June 2026 at 12:44
To: "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "sechfwd@gujarat.gov.in" <sechfwd@gujarat.gov.in>, "dci@nic.in" <dci@nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>

<helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "comfdca@gujarat.gov.in." <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

Respected Sir/s,

A gentle request to expedite as we have to commence our operations in SEZ and pending the clarity on the subject approval we are not able to initiate the processing and would impact the clients export orders.

Appreciate your earliest support and quick revert.

Thanks in advance.

With Warm Rgds.,
VIVEK MILAK

9824095027

From: Vivek - Milaks

Sent: 23 June 2026 17:25

To: ao-fdca-gnr@gujarat.gov.in; sechfwd@gujarat.gov.in; dc@nic.in; startupinnov@cdsco.nic.in; helpdesk.statedrug@cdsco.nic.in; rajeev.mishra@cii.in; himanshu.shah@cii.in; idmagsb@gmail.com; comfdca@gujarat.gov.in; druginfo@fda.hhs.gov

Subject: RE: REQUESTING CLARIFICATION REGARDING AFFIXING OF LABELS ON EMPTY CONTAINERS, SUPPLIED BY ANOTHER FDA LICENSED UNIT WITHIN SEZ (DUTY FREE - BONDED AREA)

Dear Sir/s,

As we have to commence our operations in SEZ for the subject approval and that the delay would impact the clients export orders; your earliest revert to clarifying the requirement would be much appreciable.

Thanks in advance.

With Warm Rgds.,
VIVEK MILAK

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

27 June 2026 at 12:32

To: "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "sechfwd@gujarat.gov.in" <sechfwd@gujarat.gov.in>, "dc@nic.in" <dc@nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "comfdca@gujarat.gov.in." <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

29 June 2026 at 11:08

To: "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "sechfwd@gujarat.gov.in" <sechfwd@gujarat.gov.in>, "dc@nic.in" <dc@nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "comfdca@gujarat.gov.in." <comfdca@gujarat.gov.in>

<comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

Respected Sir/s,

A gentle request to expedite as we have to commence our operations in SEZ and pending the clarification from your god office the export packing material labelling cannot be initiated and would impact the clients export orders.

THE DELAY WOULD BE CAUSING THE DELAY IN EXPORT ORDERS and thus impact the valuable forex earnings for our counrty.

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

1 July 2026 at 15:37

To: "comfdca@gujarat.gov.in." <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>

Respected Sir/s,

Appreciate your early clarification to the matter so as to enable us to commence the labelling activity on empty jars/bottles in line with the provision available.

Pending the same, the export activity of the end user in SEZ is being impacted.

With Warm Rgds.,
VIVEK MILAK

From: Vivek - Milaks

Sent: 27 June 2026 12:33

To: comfdca@gujarat.gov.in; druginfo@fda.hhs.gov

Subject: RE: REQUESTING CLARIFICATION REGARDING AFFIXING OF LABELS ON EMPTY CONTAINERS, SUPPLIED BY ANOTHER FDA LICENSED UNIT WITHIN SEZ (DUTY FREE - BONDED AREA)

Respected Sir/s,

A gentle request to expedite as we have to commence our operations in SEZ and pending the clarity on the subject approval we are not able to initiate the processing and would impact the clients export orders.

Appreciate your earliest support and quick revert.

Thanks in advance.

With Warm Rgds.,
VIVEK MILAK

9824095027

[Quoted text hidden]

cdersbia@fda.hhs.gov <cdersbia@fda.hhs.gov>

1 July 2026 at 18:07

To: "vivek@milaks.com" <vivek@milaks.com>

Cc: "dg@sezepc.in" <dg@sezepc.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "secyhfw@nic.in" <secyhfw@nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "epces@epces.in" <epces@epces.in>, "dci@nic.in" <dci@nic.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>

Dear Vivek,

Thank you for writing the Small Business and Industry Assistance, Division of Drug Information, in the United States FDA's Center for Drug Evaluation and Research.

If you are contacting us from outside of the United States, please understand that the FDA has jurisdiction over products marketed in the United States, not in other countries. You may also wish to contact the appropriate regulatory authority over these products in your country with questions or concerns.

If in the future you have additional questions, please feel free to contact us again at CDERSBIA@fda.hhs.gov.

Need additional training?

- Search the [CDER SBIA Learn](#) database for comprehensive training resources for the pharmaceutical industry, including hundreds of recordings to webinars and conferences!
- Find recordings on the CDER Small Business and Industry Assistance playlists on [YouTube](#).

Get the latest notifications for regulatory updates, webinars and conferences straight from the source - Follow SBIA on [LinkedIn](#) and subscribe to SBIA [email updates](#).

Best regards,

Priya

Pharmacist

**Small Business and Industry Assistance | Division of Drug Information
Center for Drug Evaluation and Research**

Tel: 866-405-5367

CDERSBIA@fda.hhs.gov



This communication is consistent with [21 CFR 10.85\(k\)](#) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

If you think you have received this email-message in error, please email the sender immediately at CDERSBIA@fda.hhs.gov.

[Quoted text hidden]

ref:I00Dt00TZZf.!500eq01Nbrpw:ref

Vivek - Milaks <vivek@milaks.com>

6 July 2026 at 16:57

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

Respected Sir/s,

Reference to the trailing and especially as an SEZ Entity for Export Ancillary Processing as well as Authorised Activity permitted to us through the UAC; we are yet to receive the clarification and would sincerely request your urgent intervention so as to enable us to commence the labelling activity on empty jars/bottles in line with the provision available under GFCA / CDSCO; apart from the visiting officials under the statute insisting us to hold operations.

Pending the same, the export processing of the end user in SEZ is aswell being impacted and would ultimately hamper the export aswell.

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

6 July 2026 at 22:56

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

13 July 2026 at 12:30

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

13 July 2026 at 23:02

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

A GENTLE REMINDER PLEASE >>>>'

Reference to the trailing and especially as an SEZ Entity for Export Ancillary Processing as well as Authorised Activity permitted to us through the UAC; we are yet to receive the clarification and would sincerely request your urgent intervention so as to enable us to commence the labelling activity on empty jars/bottles in line with the provision available under GFCA / CDSCO; apart from the visiting officials under the statute insisting us to hold operations.

Pending the same, the export processing of the end user in SEZ is aswell being impacted and would ultimately hamper the export aswell.

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

16 July 2026 at 13:57

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

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Vivek - Milaks <vivek@milaks.com>

20 July 2026 at 11:30

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhfw@nic.in" <secyhfw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>,

"ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

20 July 2026 at 11:39

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhw@nic.in" <secyhw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

21 July 2026 at 14:59

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhw@nic.in" <secyhw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

21 July 2026 at 15:16

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhw@nic.in" <secyhw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Vivek - Milaks <vivek@milaks.com>

21 July 2026 at 23:04

To: "comfdca@gujarat.gov.in" <comfdca@gujarat.gov.in>, "druginfo@fda.hhs.gov" <druginfo@fda.hhs.gov>, "secyhw@nic.in" <secyhw@nic.in>, "helpdesk.sugam@cdsco.nic.in" <helpdesk.sugam@cdsco.nic.in>, "ranga.cs@cdsco.nic.in" <ranga.cs@cdsco.nic.in>, "dci@nic.in" <dci@nic.in>, "ddcsz@nic.in" <ddcsz@nic.in>, "ao-fdca-gnr@gujarat.gov.in" <ao-fdca-gnr@gujarat.gov.in>, "startupinnov@cdsco.nic.in" <startupinnov@cdsco.nic.in>, "helpdesk.statedrug@cdsco.nic.in" <helpdesk.statedrug@cdsco.nic.in>, "rajeev.mishra@cii.in" <rajeev.mishra@cii.in>, "himanshu.shah@cii.in" <himanshu.shah@cii.in>, "idmagsb@gmail.com" <idmagsb@gmail.com>, EPCES <epces@epces.in>, Director General SEZEPC <dg@sezepc.in>, "jdc.kasez@gov.in" <jdc.kasez@gov.in>
Cc: "moc_epz@nic.in" <moc_epz@nic.in>

[Quoted text hidden]

Director General SEZEPC <dg@sezepc.in>

28 July 2026 at 15:02

To: harsh.mangla@ias.nic.in

Cc: secyhw@nic.in, dci@nic.in, Vivek Milak <vivek@milaks.com>

Dear Shri Mangla

Please refer to the trailing email regarding a long pending representation from a rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave) which is duly approved by Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.

The unit wants to undertake affixing of labels on empty rigid bottle/jar and to supply the same to the a customer in Kandla SEZ only and which has been duly approved / licensed by Drug Controller for manufacture of cosmetic products under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020.

The local Food and Drug Controller office visited them and asked them to obtain a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 even though they will be just affixing printed labels on empty rigid bottles/jars and supplying them to the their customer who already has license.

The unit manufactures no cosmetics.

It is requested that the office of drug controllers of India may be requested to examine the case and the local drugn controller office may be advised not to insist on a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 as the unit is not manufacturing any cosmetics. The unit will just be affixing printed labels on empty rigid bottles/jars.

Alok Chaturvedi
DG, SEZEPC

Alok V Chaturvedi, IAS(BH:86,Retd) | Director General,

Mobile +91 8130525959 | Tel: +91 11 23329770

Email : dg@epces.in

Export Promotion Council for EOUs and SEZs,

A101, 10th Floor Himalaya House 23, KG Marg, New Delhi, Delhi 110001

----- Forwarded message -----

From: **Director General SEZEPC** <dg@sezepc.in>

Date: Tue, 23 Jun 2026 at 14:48

Subject: Fwd: REQUESTING CLARIFICATION REGARDING AFFIXING OF LABELS ON EMPTY CONTAINERS, SUPPLIED BY ANOTHER FDA LICENSED UNIT WITHIN SEZ (DUTY FREE - BONDED AREA)

To: <dc@nic.in>

Cc: <secyhfw@nic.in>

Dear Dr Raghuvanshi

Please refer to the trailing email from a rigid packaging manufacturing unit based in Kandla Special Economic Zone (A duty free bonded enclave) which is duly approved by Development Commissioner, Ministry of Commerce & Industry, Kandla Special Economic Zone.

The unit wants to undertake affixing of labels on empty rigid bottle/jar and to supply the same to the a customer in Kandla SEZ only and which has been duly approved / licensed by Drug Controller for manufacture of cosmetic products under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020.

The local Food and Drug Controller office visited them and asked them to obtain a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 even though they will be just affixing printed labels on empty rigid bottles/jars and supplying them to the their customer who already has license.

The unit manufactures no cosmetics.

It is requested that the case may kindly be examined and the local Gujarat Drug Controller office may be advised not to insist on a license under the Drugs & Cosmetics Act 1940 and Cosmetic Rules 2020 as the unit is not manufacturing any cosmetics. The unit will just be affixing printed labels on empty rigid bottles/jars.

[Quoted text hidden]