



## ISSUANCE OF ONLINE BATCH NOTIFICATION FOR ANTIBIOTIC PRODUCTS

### Issuance of Online Batch Notification for Antibiotic Products

<b>Center/Office/Division:</b>	Common Services Laboratory (CSL) – Antibiotic Section FDA Cashier
<b>Classification:</b>	Simple Transaction
<b>Type of Transaction:</b>	G2B - Government to Business
<b>Who May Avail:</b>	All FDA-Licensed Pharmaceutical Establishment (Manufacturer, Importer, Distributor, and Trader)
<b>Fees to be Paid:</b>	PHP 5,000.00 + Legal Research Fee (LRF)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
<b>Pre-Evaluation</b>	
1. Clear scanned copy of the Online Batch Notification Application Form in A4 size page, completely and correctly filled out and signed by the current company pharmacist	E-mailed by the <a href="mailto:csln@fda.gov.ph">csln@fda.gov.ph</a>
2. Electronic copy (Excel format) of the Online Batch Notification Application Form	E-mailed by the <a href="mailto:csln@fda.gov.ph">csln@fda.gov.ph</a>
3. Commitment Letter for submission	Applicant
4. Clear scanned copy of valid License to Operate (as manufacturer/trader/exporter, whichever is applicable)	Applicant
5. Clear scanned copy of valid Certificate of Product Registration (CPR) and/or Certificate for Variation (COV) application	Applicant



CHECKLIST OF REQUIREMENTS	WHERE TO SECURE										
6. Clear scanned / electronic copy of valid Certificate of Analysis of the finished product reflecting similar batch/lot number with the sample submitted, batch size, theoretical and actual yield	Applicant										
7. For imported products (1) Clear scanned / electronic copy of commercial invoice and/or packing list reflecting the expiry date and batch/lot number of the product or any document to prove the actual volume of importation; and (2) Transport Documents (Bill of Lading / Airway Bill / Seaway Bill) for the particular shipment. The volume of importation must be the same in the application form	Applicant										
8. Clear scanned / electronic copy of Notice of Minor Variation/s (if applicable)											
9. Clear scanned / electronic copy of updated Document Tracking Number or status of the request (if applicable)											
<p>10. Image of the representative sample (as illustrated below) including the product insert and box in commercial presentation bearing the Principal Label, Batch/Lot No., Company Address, Registration No., Manufacturing and Expiration Date.</p> <table border="1" data-bbox="248 1075 1144 1335"> <thead> <tr> <th data-bbox="248 1075 725 1118">SAMPLE TYPE</th> <th data-bbox="725 1075 1144 1118">QUANTITY REQUIRED</th> </tr> </thead> <tbody> <tr> <td data-bbox="248 1118 725 1161">Tablet or capsule</td> <td data-bbox="725 1118 1144 1161">1 blister pack or foil strip</td> </tr> <tr> <td data-bbox="248 1161 725 1204">Oral Suspension</td> <td data-bbox="725 1161 1144 1204">1 bottle per presentation</td> </tr> <tr> <td data-bbox="248 1204 725 1294">Granules or Powder for Suspension</td> <td data-bbox="725 1204 1144 1294">1 bottle</td> </tr> <tr> <td data-bbox="248 1294 725 1335">Cream or Ointment</td> <td data-bbox="725 1294 1144 1335">1 tube per presentation</td> </tr> </tbody> </table>	SAMPLE TYPE	QUANTITY REQUIRED	Tablet or capsule	1 blister pack or foil strip	Oral Suspension	1 bottle per presentation	Granules or Powder for Suspension	1 bottle	Cream or Ointment	1 tube per presentation	Applicant
SAMPLE TYPE	QUANTITY REQUIRED										
Tablet or capsule	1 blister pack or foil strip										
Oral Suspension	1 bottle per presentation										
Granules or Powder for Suspension	1 bottle										
Cream or Ointment	1 tube per presentation										



CHECKLIST OF REQUIREMENTS		WHERE TO SECURE
Ophthalmic, Otic, Nasal Drops	1 bottle per presentation	
Injectables	1 ampoule or vial per presentation	
Liquid Preparations	1 vial	
Solid Preparations	1 vial	
<b>Post-Evaluation</b>		
1. Clear scanned copy / electronic copy of the Proof of Payment		Landbank / Online Banking
2. Two (2) sets of NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ON-LINE FORM with the company pharmacist's original signature on Page 3. 1.1. Applicants that submitted Notarized BN Application Form must submit it, together with the APPROVED BN FORM (with or without the notarial requirements for the latter) with the company pharmacist's original signature on Page 3. 1.2. Post-submission for nonnotarized BN application/s must follow the guidelines of the notarial requirements of the FDA Circular No.2017-011 - Batch Notification under II. SPECIFIC INSTRUCTIONS 2.e.: "...dates should be within the week of actual submission of the BN Form." or within 5 working days from the date of notarization. Submission of antedated application/s will not be accepted.		Applicant
3. Other required documents		Applicant
4. Commitment Letter		Applicant
5. Representative Sample		Applicant



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Download, accomplish, print, and scan the Online Batch Notification Application Form; take a clear image of the representative sample and its packaging; and submit an email request with the link of the compressed/zipped documents or attached electronic and scanned copies of the requirements to <a href="mailto:cslbn@fda.gov.ph">cslbn@fda.gov.ph</a> .	1.1. Checks email requests lodged at <a href="mailto:cslbn@fda.gov.ph">cslbn@fda.gov.ph</a> .	None	1 Minute	<i>Food-Drug Regulation Officer / Laboratory Technician</i> CSL-Antibiotic Section
	1.2. Reviews the application for completeness of requirements and correctness of the Application Form and the actual sample submitted.	None	10 Minutes	
	1.3. If found non-compliant, the application is returned, and the Applicant will be informed of the reason/s for rejection.	None	2 Minutes	



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Note: Applicant is advised to re-submit all documents the next working day.			
	1.4. If found compliant, the following steps are performed: <ul style="list-style-type: none"> <li>• Assigns BN Number and initials of the evaluator; and</li> <li>• Issues payment details for each application received.</li> </ul>	None	4 Minutes	
2. Proceeds to their preferred payment option; submits a clear copy of the proof of payment to <a href="mailto:cashierposting@fda.gov.ph">cashierposting@fda.gov.ph</a> and copy furnish (cc:) to <a href="mailto:csln@fda.gov.ph">csln@fda.gov.ph</a> .	2.1. Posting of payment.	PHP 5,000/ application + LRF	Refer to FDA Cashier Citizen's Charter	<i>Cashier Staff</i> FDA Cashier
	2.2. Reviews e-mailed proof of payment and completes the portion of Payment Information on the online BN application form.	None	3 Minutes	<i>Food-Drug Regulation Officer / Laboratory Technician</i> CSL-Antibiotic Section
	2.3. Stamps the name and electronic signature of the	None	3 Minutes	



CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	approving personnel on the online BN application form.			
	2.4. Sends approved and signed Online BN application form	None	2 Minutes	
3. Submits the hard copies of the notarized approved online BN application and representative sample to the FDA Central Office.	3.1. Checks for the correctness and completeness of the documents.	None	3 Minutes	
	3.2. Records the BN Number to the Releasing Logbook and releases the signed BN form to the applicant.	None	2 Minutes	
	<b>TOTAL</b>		<b>30 Minutes</b>	

**NOTES:**

1. Applications are accommodated online through [cslbn@fda.gov.ph](mailto:cslbn@fda.gov.ph) from 9:00 AM to 2:00 PM, Mondays to Fridays except holidays and suspension of work when deemed necessary (e.g., acts of nature). Applications including proof of payments submitted beyond the given schedule will be processed on the next working day.
2. The approved BN shall be paid within 5 working days, any late payment will invalidate your application. Any payment before the approval of your application shall be voided.
3. Walk-in post-submission of online applications will be accepted every Wednesday from 9:00 AM to 4:00 PM only, except during holidays and suspension of work. All post-submission beyond the set schedule shall not be accommodated. Only those post-submission requirements forwarded via courier, dispatch riders, or other forwarding services with no definite arrival time shall be accepted by the on-duty guard, which shall be subjected to further evaluation and shall not guarantee acceptance by the CSL.



4. Submit only one (1) hard copy of the NOTARIZED APPROVED BATCH NOTIFICATION APPLICATION ONLINE FORM, with the company pharmacist's signature (Page 3 of BN Form) together with the required documents and the representative sample within twenty (20) working days. Failure to submit requirements and samples within the required timeline will be subject to termination of the application and non-refundable payment.
5. Commencement of Day 1 processing is applicable only to applications with verified and posted payment by the FDA Cashier.