



Rod R. Blagojevich, Governor
Eric E. Whitaker, M.D., M.P.H., Director

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To Whom It May Concern:

The following is a copy of a Notification form for the inclusion of a generic drug product in the *Illinois Notification List for the Drug Product Selection Program*. The Notification List lists legend reference drugs and the accepted manufacturers or federally approved application holders of generic products, which may be substituted by Illinois pharmacists at lesser cost to the patient when the prescriber has not prohibited interchange and the patient (or his/her agent) has been informed of and agreed to the interchange. The Notification List form may be duplicated for additional product submissions, however, only this format will be accepted.

Please provide all of the following with your completed Notification form:

1. A copy of your FDA ANDA or NDA approval letter, if available;
2. For those products which the FDA requires biostudies, one copy of the biostudy summary approved by the FDA for your ANDA/NDA and one copy of the completed Biodata Analysis Form. See Requirements for Biodata Summary Submission document.

Questions on this process may be directed to Joseph J. Bogdan, Pharm. D., J.D., Manager, Drugs and Medical Devices Programs, Division of Food, Drugs and Dairies, Illinois Department of Public Health, 525 West Jefferson Street, Springfield, IL 62761-0001, telephone (217) 785-2439, TTY (800) 547-0466, facsimile (217) 782-0943, or e-mail at jbogdan@idph.state.il.us

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Illinois Department of Public Health
Division of Food, Drugs and Dairies
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**NOTIFICATION FORM FOR INCLUSION OF DRUG PRODUCT IN THE ILLINOIS
DRUG PRODUCT SELECTION NOTIFICATION LIST**

Section 25 of the Pharmacy Practice Act of 1987, 225 ILCS 85/25, and the Section 3.14 of the Illinois Food, Drug and Cosmetic Act, 410 ILCS 620/3.14 provide for the publication and maintenance of the *Illinois Notification List for the Drug Product Selection Program*. The information requested below, as well as information which we may later request, will begin the process of determining whether your company's drug products will be included in the *Illinois Notification List*.

Instructions:

- Notification forms must be typewritten; use this form or an exact copy. Answer all questions.
- One notification per form. If this is a single ingredient product, several strengths may be listed on one notification form. Do not submit additional notification forms for different package sizes.
- If additional space is required, please attach documents and indicate on the notification form.
- Address notification forms and questions to the address above.
- Provide a copy of your FDA approval letter.
- For those products which the FDA requires biostudies, provide one copy of the biostudy summary approved by the FDA for your ANDA and one copy of the completed Biodata Analysis Form.

Notification forms must be submitted no later than 60 days prior to product substitution which may occur in the State of Illinois.

NOTIFICATION FORM FOR INCLUSION OF DRUG PRODUCT IN THE ILLINOIS DRUG PRODUCT SELECTION NOTIFICATION LIST

1. Name of manufacturer/application holder:	2. Date of application:
3. Mailing address of manufacturer/application holder:	4. Address of manufacturing site (if different):
5. Name of contact person (for clarification of this application):	6. Contact person's telephone number and e-mail address:
7. Reference brand for which above is a substitute:	8. Dosage form:
9. Generic name and strength(s) of drug product(s) submitted for inclusion in the Illinois Formulary for single ingredient items OR name and amount of each active ingredient:	
10. Does each batch of this drug product conform with official standards prior to being marketed? _____ Yes _____ No	11. Date last inspected by FDA for CGMP compliance:
12. Date of drug product's FDA approval:	13. Is this drug product: Manufactured under an ANDA? _____ Yes _____ No Manufactured under the NDA? _____ Yes _____ No
14. Is this product subject to a bioequivalence waiver? _____ Yes _____ No If yes, please provide a copy.	15. Does the name of the manufacturer appear on all distributors' labels? _____ Yes _____ No
16. National Drug Code:	17. Usual cost to pharmacies (AWP/100 or specify)

I agree to inform the Illinois Department of Public Health in writing of any changes in the information listed in this application within 30 days of such change, and do certify that the information submitted is, to the best of my knowledge, correct and that this product is not in violation of either Federal or State Law.

Signature

Printed name

Title

Illinois Department of Public Health

REQUIREMENTS FOR BIODATA SUMMARY SUBMISSION

- I. The biostudy submission should contain: the objective, the study design, the number of subjects, inclusion/exclusion criteria, test and reference product descriptions, dose, sampling schedules, safety monitoring, fasting/meals, washout, results, discussion, and conclusion. Biostudies submitted must include completed Biodata Analysis Forms, indicating the analyte studied in a specified medium (plasma, serum, or urine). If additional analytes (i.e., metabolites) are evaluated, additional sheets should be attached.

- II. Complete the Biodata Analysis Form, including the following parameters:
 - A. Log-transformed area under the plasma concentration vs. time curve from time zero to the last detectable concentration Ln AUC_(0-LDC)

 - B. Log-transformed maximum plasma concentration Ln C_{max}

 - C. Time to reach C_{max} T_{max}

- III. To qualify as “Statistically Equivalent” in a standard cross over study, at a minimum, the following criteria must be met:
 - A. Mean values for Ln AUC_(0-LDC), Ln C_{max}, and T_{max} must be provided.

 - B. The 90% confidence interval (90% CI) for Ln AUC_(0-LDC), and Ln C_{max} must be provided, and must be within 80-125%.

 - C. If the study is given under FED conditions, the geometric mean ratio [GM Ration (%)] for Ln AUC_(0-LDC) and Ln C_{max} must be within 80-125% for comparison of generic fed and reference fed treatments.

 - D. At the discretion of the Department, other data may be requested.

Illinois Department of Public Health

Comparative Dissolution Requirements

For extended-release, solid-oral dosage form drug products for which biostudies are not required or reviewed by the FDA:

Use twelve individual doses from the same lot for both the reference product and the generic product for each active ingredient.

- **Medium:**
Dissolution profiles should be generated in 900ml at +/- 0.5 in the following pH ranges:
 - pH 1.0-1.5
 - pH 4.0-4.5
 - pH 6.0-6.5
 - pH 7.0-7.5

- **Apparatus**
 - Capsules**

100 RPM using USP Apparatus 1 (Rotating Basket)

 - Tablets**

50 RPM **and** 75 RPM using USP Apparatus 2 (Paddles)

- **Time:** 1, 2, 4, and 6 hours and every 2 hours thereafter until 80% of the product is released.

- **Statistical Evaluation:**

Provide analysis to show the difference between the reference and the test product at each time point for each pH.

Provide a Time vs. Concentration graph for each pH.

- Content uniformity testing should be performed in accordance with USP methods, unless stricter parameters have been identified for the product.