

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-301

CORRESPONDENCE

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: May 15, 2001
TO: File for NDA 21-301
FROM: Steve McCort
SUBJECT: Final draft labeling for NDA 20-301 dated May 15, 2001

A labeling amendment dated May 15, 2001, for NDA 21-301, Levoxyl was submitted. The draft labeling submitted contained revised draft labeling for the package insert, container, box label and blister packages.

The labeling was reviewed by the Division and found to be acceptable. The recommendation is that the submitted draft labeling dated May 15, 2001, be approved.

/S/

Stephen McCort,
Project Manager, HFD-510

Concurrence: D Lewis 5-15-01/D Wu 5-15-01/J Temeck 5-15-01/K Davis 5-15-01
H Ahn 5-15-01

MEMORANDUM

**APPEARS THIS WAY
ON ORIGINAL**

WITHHOLD 94 PAGES

Draft

Labeling

**LEVOTHYROXINE LABELING
TEMPLATE (VERSION 4)
MAY 15, 2001**

**APPEARS THIS WAY
ON ORIGINAL**

WITHHOLD 14 PAGES

Draft

Labeling

JULY 28, 2001 DRAFT LABELING

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Draft

Labeling

RECORD OF TELEPHONE CONVERSATION/MEETING	DATE: 4-12-01
<p>I called Ms. Cafmeyer and requested the method by which the statistical analyses (assay regressions), which were provided in the 4-06-01 amendment, were done. Ms. Cafmeyer linked the phone conversation up with Ms. Elaine Strauss (who did the analyses), and the following answers were obtained:</p>	NDA NUMBER: 21-301
<ol style="list-style-type: none"> 1) The regressions were performed utilizing a Texas Instruments calculator program. 2) The regression involved plotting the data from Time zero through 15 months, using percent loss of potency as the y-axis variable. 3) The graphs were plotted using Microsoft Excel®. 4) The final results were stated as percent potency loss at 24 months. 	PRODUCT NAME: Levoxyt® (levothyroxine sodium tablets, USP)
<p>I also inquired whether the blister-packs had been stability tested at more strenuous storage conditions (e.g., 30°C/60 % RH or 40°C/75 % RH). According to Ms. Strauss, this had not been done. The following reasons were given:</p>	FIRM NAME: Jones Pharma Incorporated (JPI)
<ol style="list-style-type: none"> 1) JPI thought that the unit-dose-packaged product would not survive thermal stress of these conditions. 2) The Unit-dose packaging was usually dispensed in hospital settings. 	NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Nancy Cafmeyer, VP Regulatory Affairs
<p>I stated my concerns, as follows:</p> <ol style="list-style-type: none"> 1) The room temperature storage statement allows for excursions from 15-30°C; thus some stability data accumulated at 30°C would be necessary to render that statement suitable for the unit-dose presentation. 2) The long-term stability data for the unit-dose packaged product was essentially identical to that for the product packaged in HDPE bottles. <p>I said that I would consult with DG Wu (team leader) as to the acceptability of providing some 30°C/60 % RH stability data for the unit dose packaging as some sort of post-approval commitment.</p>	TELEPHONE NUMBER: (314) 576-6100 X 3070
SIGNATURE:	DIVISION: DMEDP

<p>I called Ms. Cafmeyer and requested several stability data points, which were omitted from the 2-27-01 amendment. The submission of these data points would complete the stability testing through 15 months of the 24-month controlled room temperature studies, and also complete the 12-month intermediate storage condition studies. I also asked whether JPI had performed a statistical analysis of the assay regression data (e.g., 95 % 2-sided extrapolative study, in order to estimate a date of expiry). I stated that this was not required, but could possibly help the Agency in our assignment of a shelf life for the drug product, in the absence of completed long-term stability studies.</p>	<p>NDA NUMBER: 21-301</p>
<p>Ms. Cafmeyer said she would FAX me the missing data points, and follow up with a hard copy (official amendment), and that she would look into whether statistical analysis had been/ could be/ would be considered.</p>	<p>PRODUCT NAME: Levoxy® (levothyroxine sodium tablets, USP)</p>
	<p>FIRM NAME: Jones Pharma Incorporated (JPI)</p>
	<p>NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD: Nancy Cafmeyer, VP Regulatory Affairs</p>
	<p>TELEPHONE NUMBER: (314) 576-6100 X 3070</p>
<p>SIGNATURE:</p>	<p>DIVISION: DMEDP</p>

APPEARS THIS WAY
ON ORIGINAL

LEVOTHYROXINE LABELING TEMPLATE

NDA 21-301

DRUG: Levoxyl (Levothyroxine Sodium Tablets, USP)

FIRM: JONES PHARMA INC.

We are sending you a **Levothyroxine Labeling Template** which incorporates the latest revisions in the package insert for Levothyroxine applications. Please revise your draft labeling submitted to your pending NDA 21-301 dated July 28, 2001.

In you reply submit all labeling including package insert, container and carton labels (colored copies) for all strengths. This should be submitted in duplicate as a hard copy. In addition submit as a desk copy the package insert, container and carton labels to Steve McCort an electronic version on a 3.5 diskette. The package insert should be submitted as a word 7.0 document as well as a PDF document. The carton and container labeling should be submitted in PDF only.

If you have any questions or wish to discuss the labeling revisions before sending back the labeling, please call Steve McCort, Project Manager at 301-827-6415.

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ON ORIGINAL**

LEVOTHYROXINE LABELING TEMPLATE

NDA 21-301

DRUG: Levoxyl (Levothyroxine Sodium Tablets, USP)

FIRM: JONES PHARMA INC.

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OK for FAX:

 /S/ 5-10-07

David Orloff, M.D.
Division Director, HFD-510

APPEARS THIS WAY
ON ORIGINAL

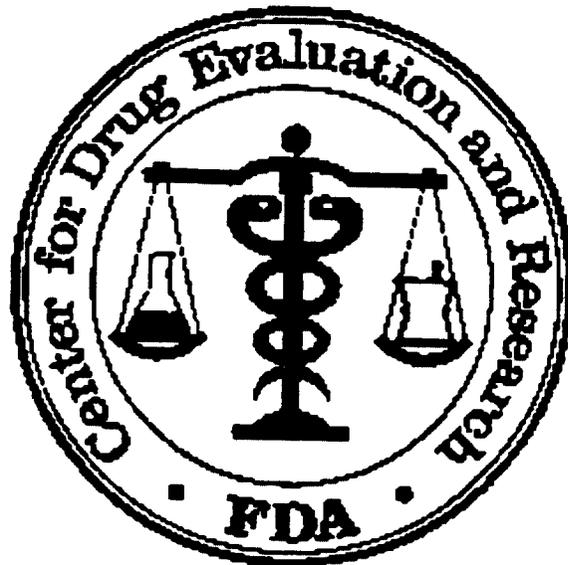
WITHHOLD 14 PAGES

Draft

Labeling

FOOD AND DRUG ADMINISTRATION
DIVISION OF METABOLIC AND
ENDOCRINE DRUG PRODUCTS, HFD-510
DOCUMENT CONTROL ROOM 14B-19
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: MARCH 15, 1999



TO:

Name: Nancy Cafmeyer

Fax No: 314-469-5743

Phone No: 314-576-6100

Location: Jones Medical

FROM:

Name: Steve McCort

Fax No: 301-443-9282

Phone No: 301-827-6415

Location: FDA, Division of
Metabolic and Endocrine
Drug Products, HFD-510

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copy, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above the above address by mail. Thank you.

Comments:

**COMMENTS TO MARCH 4, 1999 LETTER TO FDA REGARDING PROPOSED
STUDIES FOR LEVOTHYROXINE SODIUM TABLETS**

**APPEARS THIS WAY
ON ORIGINAL**

**FDA RESPONSE TO LETTER DATED MARCH 4, 1999, FROM JONES MEDICAL
REGARDING PROPOSED STUDIES FOR LEVOTHYROXIN SODIUM TABLETS**

In the March 4, 1999 letter to the Agency, the firm asked the following question:

"Do the multi-point dissolution profiles of all strengths to be marketed (according to the biostudy protocol) need to be completed prior to the start of the biostudy and submitted in the initial IND submission or can just the strengths in the study (low, middle, and high) be done initially and the strengths submitted with the biostudy completion report?"

FDA RESPONSE: The sponsor can complete dissolution profiles for just the strengths proposed in the study (low, middle and high) or for all strengths to be marketed, as they choose. However, it would be better if the sponsor completes the dissolution study for all strengths prior to the initiation of the IND.

**APPEARS THIS WAY
ON ORIGINAL**

MEMORANDUM OF TELECON

DATE January 23, 2001

APPLICATION NUMBER: NDA 21-301

BETWEEN:

Name: Nancy Cafmeyer, Regulatory Affairs

Phone: 314-576-6100

Representing: Jones Pharmaceutical

AND

Name: Steve Johnson, Pharm D., Biopharm Reviewer
Steve McCort, Project Manage

SUBJECT: Biopharm issues

The meeting was called to gain an understanding of what additional information would needed for dissolution studies. Dr. Steve Johnson had a concern regarding the data for the 5 minute interval in the dissolution study. This indicated that the drug substance had a higher than expected value for L-thyroxine and that this suggested that there may be an absorption and or filter problem. The 10-minute reading showed a lower value suggesting that the product would not meet the USP 24 standard of greater than 80% after 45 minutes.

The Firm said that this was due to the technique and not to the results. The result indicated that the values at 45 min did meet the USP 24 requirement of greater than 80% for each lot. Dr. Johnson asked the Firm to send that data to the file for NDA 21-301 and that should fulfill the requirement for dissolution.

In a post conversation with the firm, Nancy Cafmeyer gave reference where this information could be obtained, and therefore would not need additional summation material be sent to the NDA.

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/S/

SIGNER'S NAME and TITLE

1-23-2001

cc:

Archival IND/NDA 21-301

HFD-XXX/Division Files

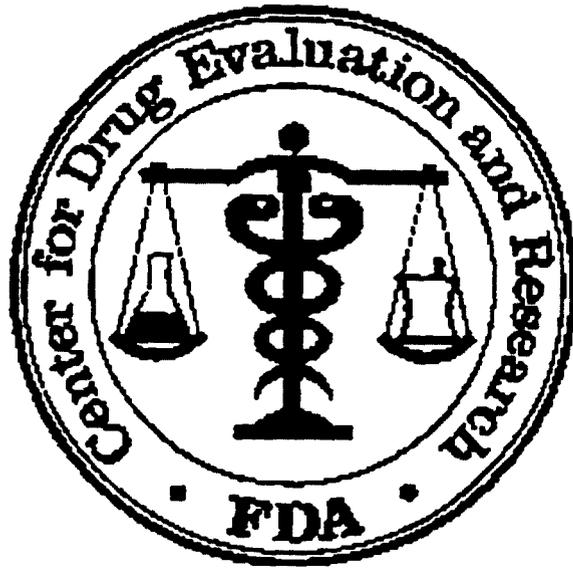
HFD-XXX/Reviewers and Team Leaders

Drafted by: INITIALS/DATE

APPEARS THIS WAY
ON ORIGINAL

FOOD AND DRUG ADMINISTRATION
DIVISIONS OF METABOLIC AND
ENDOCRINE DRUG PRODUCTS, HFD-510
DOCUMENT CONTROL ROOM 14B-19
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

DATE: July 16, 1999



BEST POSSIBLE COPY

TO:

Name: Nancy Casmeyer

Fax No: 314-469-5743

Phone No: 314-576-6100

Location: Jones Medical

FROM:

Name: Steve McCort

Fax No: 301-443-9282

Phone No: 301-827-6415

Location: FDA, Division of
Metabolic and Endocrine
Drug Products, HFD-510

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Comments:

Comments for L-thyroxine when NDA submitted (clinical):

CC: HFD-510 / Subject File / L-Thyroxine-997
HFD-510 / SMCCORT

The following comment pertains to additional information needed when the NDA for L-Thyroxine is submitted:

Summarize, by individual bioavailability study, the results of each safety parameter monitored, noting any abnormalities that occurred and if they were clinically significant.

APPEARS THIS WAY
ON ORIGINAL

Advisory meeting was not needed.

Proposed Project

Assessment of Exposure to Arsenic through Household Water—New—National Center for Environmental Health (NCEH). Arsenic is a naturally occurring element present in food and water as both inorganic and organic complexes. Epidemiologic evidence shows a strong link between ingestion of water containing inorganic arsenic and an increase in a wide variety of cancers (e.g., bladder cancer). Consumption of contaminated food is the major source of arsenic exposure for the majority of United States citizens. There are some areas of the United States where

elevated levels of arsenic in water occur with appreciable frequency. In such areas, ingestion of water can be the dominant source of arsenic exposure. Currently, the preferred method of treatment of private, domestic well water containing elevated levels of arsenic is point-of-use (POU) devices. The acceptability of bottled water and POU treatment systems as effective means of managing arsenic exposure is based on the assumption that other water exposures such as bathing, brushing of teeth, cooking, and occasional water consumption from other taps contribute relatively minor

amounts to a person's total daily intake of arsenic.

We propose to conduct a study to methodically test the validity of the commonly-made assumption that secondary exposures such as bathing will not result in a significant increase in arsenic intake over background dietary levels. Specifically, we are interested in assessing urine arsenic levels among individuals where ingestion of arsenic-containing water is controlled by either POU treatment or use of bottled water, combined with use of short-term diaries to record diet, water consumption, and bathing frequency. Total annual burden is 510.

Respondents	Number of respondents	Responses/ respondent	Average burden response (in hours)
Prescreening postcard completion			
Recruiting telephone interview	1,000	1	5/60
Survey interview (in person)	320	1	15/60
Biologic specimen collection	520	1	30/60
	520	1	10/60

Dated: April 20, 2000.

Charles W. Gollmar,
Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-10351 Filed 4-25-00; 8:45 am]
BILLING CODE 4162-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF-PA-MS-2000-03B]

Fiscal Year 2000 Discretionary Announcement of the Availability of Funds and Request for Applications for Nationwide Expansion Competition of Early Head Start; Correction

AGENCY: Administration for Children, Youth and Families, ACF, DHHS.
ACTION: Correction.

SUMMARY: This document contains a correction to the Notice that was published in the Federal Register on Tuesday, February 29, 2000.

On page 10797, in the State of Colorado, Arapahoe County, in the local community column the following service area should be added: Colfax Avenue (county line) on the North, Mississippi Avenue on the South, Chambers Road on the East and Yosemite Street (county line) on the West. This area is currently being served and is not open for competition to new

Early Head Start programs. The remaining part of Arapahoe County is not currently being served and is open to competition to new Early Head Start programs.

On page 10797, in the State of Colorado, in Denver County, in the local community column for the city of Denver, after the service areas numbered (1)-(4), the following service areas should be added in the city of Denver: "(5) the area bounded by 52nd Avenue on the North, Alameda Boulevard on the South, Broadway Avenue on the East and Sheridan Boulevard on the West." "(6) Beginning at north Broadway and 38th avenue, go east to Yosemite; Yosemite south to 11th Avenue, 11 Avenue west to Quebec; Quebec south to Hampden, Hampden west to Broadway; Broadway north to 35th Avenue." "(7) Beginning at north 54th Avenue and Peoria, go 54th east to Chambers; Chambers south to I-70, I-70 West to Peoria, Peoria north to 54th Avenue." "These three areas (5) (6) and (7) are currently being served in the city of Denver in addition to service areas (1) through (4). These seven service areas in the city of Denver are not open to competition to new Early Head Start programs.

On page 10802, of the State of Minnesota, Hennepin County, in the local community column delete "City of North Minneapolis" and replace with "Minneapolis, Brooklyn Park, Golden Valley, and Richfield."

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1-800-351-

2293 or send an email to ehs@icgnet.com. You can also contact Judith Jerald; Early Head Start, Head Start Bureau at (202) 205-8074.

Dated: April 20, 2000.

Patricia Montoya,
Commissioner, Administration on Children, Youth and Families.

[FR Doc. 00-10378 Filed 4-25-00; 8:45 am]
BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0314]

Prescription Drug Products; Levothyroxine Sodium; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that manufacturers who were marketing orally administered drug products containing levothyroxine sodium on or before August 14, 1997, may continue to market these products without approved applications until August 14, 2001. FDA is extending by 1 year the compliance date given in the notice published in the Federal Register of August 14, 1997 (62 FR 43535). The agency is taking this action to give manufacturers additional

time to conduct studies and to prepare applications.

EFFECTIVE DATE: April 26, 2000.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 14, 1997 (62 FR 43535), FDA announced that orally administered drug products containing levothyroxine sodium are new drugs and required manufacturers to have approved applications as a condition of marketing. The notice advised that manufacturers who were marketing levothyroxine sodium drug products on or before August 14, 1997, may continue to market their products until August 14, 2000.¹ The notice stated that a manufacturer who marketed a levothyroxine sodium drug product without an approved application after that date would be subject to regulatory action.

FDA permitted this period of continued marketing because it regards levothyroxine sodium products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. FDA has now concluded that manufacturers may need additional time to conduct studies and to prepare applications. Therefore, the agency extends by 1 year the compliance date given in the Federal Register notice of August 14, 1997, to permit continued marketing of these products until August 14, 2001.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Regulatory Affairs (21 CFR 5.20).

Dated: April 18, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.
[FR Doc. 00-10322 Filed 4-25-00; 8:45 am]
BILLING CODE 4160-01-F

¹ After August 14, 1997, a new levothyroxine drug product may not be introduced into the market unless FDA has approved an application for that product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 19, 2000, 10 a.m. to 2 p.m.

Location: Holiday Inn, Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville MD, 301-827-7001, email: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation of the data and rationale for the regulatory action regarding the withdrawal from the U.S. market of Rezulin™ (troglitazone, Parke-Davis Pharmaceutical Research, a Division of Warner-Lambert) for the treatment of type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 15, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 15, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 17, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-10321 Filed 4-25-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB 0915-0174)—EXTENSION

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under Section 621 of Title VI and Section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the Section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

HUMAN SERVICES

Food and Drug Administration

(Docket No. 97F-0338)

General Electric Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that General Electric Co. has filed a petition proposing that the food additive regulations be amended to change the intrinsic viscosity specifications for poly(2,6-dimethyl-1,4-phenylene) oxide resins intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4551) has been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620-9364. The petition proposes to amend the food additive regulations in § 177.2460 Poly(2,6-dimethyl-1,4-phenylene) oxide resins to change the intrinsic viscosity specifications for the poly(2,6-dimethyl-1,4-phenylene) oxide resins intended for use in contact with food from "not less than 0.40 deciliter per gram" to "not less than 0.30 deciliter per gram" as determined by ASTM method D1243-79.

The agency has determined under 21 CFR 25.24(9) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 31, 1997.

Alan M. Raitz,
Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
(FR Doc. 97-21436 Filed 8-13-97; 8:45 am)

BILLING CODE 9100-01-7

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

(Docket No. 97N-0314)

Prescription Drug Products; Levothyroxine Sodium

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that orally administered drug products containing levothyroxine sodium are new drugs. There is new information showing significant stability and potency problems with orally administered levothyroxine sodium products. Also, these products fail to maintain potency through the expiration date, and tablets of the same dosage strength from the same manufacturer vary from lot to lot in the amount of active ingredient present. This lack of stability and consistent potency has the potential to cause serious health consequences to the public. Manufacturers who wish to continue to market orally administered levothyroxine sodium products must submit new drug applications (NDA's); manufacturers who contend that a particular drug product is not subject to the new drug requirements of the Federal Food, Drug, and Cosmetic Act (the act) should submit a citizen petition. FDA has determined that orally administered levothyroxine sodium products are medically necessary, and accordingly the agency is allowing current manufacturers 3 years to obtain approved NDA's.

EFFECTIVE DATE: August 14, 1997.

DATES: A citizen petition claiming that a particular drug product is not subject to the new drug requirements of the act should be submitted no later than October 14, 1997.

After August 14, 2000, any orally administered drug product containing levothyroxine sodium, marketed on or before the date of this notice, that is introduced or delivered for introduction into interstate commerce without an approved application, unless found by FDA to be not subject to the new drug requirements of the act under a citizen petition submitted for that product, will be subject to regulatory action.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 97N-0314 and directed to the appropriate office named below:

Applications under section 505 of the act (21 U.S.C. 355): Documents and Records Section (HFA-224), 5600 Fishers Lane, Rockville, MD 20857.

Citizen petitions (see § 10.30 (21 CFR 10.30)) contending that a particular drug product is not subject to the new drug requirements of the act: Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

Requests for an opinion on the applicability of this notice to a specific product: Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

Levothyroxine sodium is the sodium salt of the levo isomer of the thyroid hormone thyroxine (T₄). Thyroid hormones affect protein, lipid, and carbohydrate metabolism; growth; and development. They stimulate the oxygen consumption of most cells of the body, resulting in increased energy expenditure and heat production, and possess a cardiostimulatory effect that may be the result of a direct action on the heart.

Levothyroxine sodium was first introduced into the market before 1962 without an approved NDA, apparently in the belief that it was not a new drug. Orally administered levothyroxine sodium is used as replacement therapy in conditions characterized by diminished or absent thyroid function such as cretinism, myxedema, nontoxic goiter, or hypothyroidism. The diminished or absent thyroid function may result from functional deficiency, primary atrophy, partial or complete absence of the thyroid gland, or the effects of surgery, radiation, or antithyroid agents. Levothyroxine sodium may also be used for replacement or supplemental therapy in patients with secondary (pituitary) or tertiary (hypothalamic) hypothyroidism.

Hypothyroidism is a common condition. In the United States, 1 in every 4,000 to 5,000 babies is born hypothyroid. Hypothyroidism has a prevalence of 0.5 percent to 1.3 percent in adults. In people over 60, the prevalence of primary hypothyroidism

Proposed Project

Assessment of Exposure to Arsenic through Household Water—New—National Center for Environmental Health (NCEH). Arsenic is a naturally occurring element present in food and water as both inorganic and organic complexes. Epidemiologic evidence shows a strong link between ingestion of water containing inorganic arsenic and an increase in a wide variety of cancers (e.g., bladder cancer). Consumption of contaminated food is the major source of arsenic exposure for the majority of United States citizens. There are some areas of the United States where

elevated levels of arsenic in water occur with appreciable frequency. In such areas, ingestion of water can be the dominant source of arsenic exposure. Currently, the preferred method of treatment of private, domestic well water containing elevated levels of arsenic is point-of-use (POU) devices. The acceptability of bottled water and POU treatment systems as effective means of managing arsenic exposure is based on the assumption that other water exposures such as bathing, brushing of teeth, cooking, and occasional water consumption from other taps contribute relatively minor

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Recruiting telephone interview	320	1	15/60
Survey interview (in person)	520	1	30/60
Biologic specimen collection	520	1	10/60

Dated: April 20, 2000.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00-10351 Filed 4-25-00; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. ACYF-PA-HS-2000-03B]

Fiscal Year 2000 Discretionary Announcement of the Availability of Funds and Request for Applications for Nationwide Expansion Competition of Early Head Start; Correction

AGENCY: Administration for Children, Youth and Families, ACF, DHHS.

ACTION: Correction.

SUMMARY: This document contains a correction to the Notice that was published in the Federal Register on Tuesday, February 29, 2000.

On page 10797, in the State of Colorado, Arapahoe County, in the local community column the following service area should be added: Colfax Avenue (county line) on the North, Mississippi Avenue on the South, Chambers Road on the East and Yosemite Street (county line) on the West. This area is currently being served and is not open for competition to new

Early Head Start programs. The remaining part of Arapahoe County is not currently being served and is open to competition to new Early Head Start programs.

On page 10797, in the State of Colorado, in Denver County, in the local community column for the city of Denver, after the service areas numbered (1)-(4), the following service areas should be added in the city of Denver:

"(5) the area bounded by 52nd Avenue on the North, Alameda Boulevard on the South, Broadway Avenue on the East and Sheridan Boulevard on the West."
 "(6) Beginning at north Broadway and 38th avenue, go east to Yosemite; Yosemite south to 11th Avenue, 11 Avenue west to Quebec; Quebec south to Hampden, Hampden west to Broadway; Broadway north to 35th Avenue."
 "(7) Beginning at north 54th Avenue and Peoria, go 54th east to Chambers; Chambers south to I-70, I-70 West to Peoria, Peoria north to 54th Avenue." These three areas (5) (6) and (7) are currently being served in the city of Denver in addition to service areas (1) through (4). These seven service areas in the city of Denver are not open to competition to new Early Head Start programs.

On page 10802, of the State of Minnesota, Hennepin County, in the local community column delete "City of North Minneapolis" and replace with "Minneapolis, Brooklyn Park, Golden Valley, and Richfield."

FOR FURTHER INFORMATION CONTACT: The ACYF Operations Center at 1-800-351-

2293 or send an email to ehs@cgnet.com. You can also contact Judith Jerald, Early Head Start, Head Start Bureau at (202) 205-8074.

Dated: April 20, 2000.

Patricia Montoya,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 00-10378 Filed 4-25-00; 8:45 am]

BILLING CODE 4164-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0314]

Prescription Drug Products; Levothyroxine Sodium; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that manufacturers who were marketing orally administered drug products containing levothyroxine sodium on or before August 14, 1997, may continue to market these products without approved applications until August 14, 2001. FDA is extending by 1 year the compliance date given in the notice published in the Federal Register of August 14, 1997 (62 FR 43535). The agency is taking this action to give manufacturers additional

time to conduct studies and to prepare applications.

EFFECTIVE DATE: April 26, 2000.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 14, 1997 (62 FR 43535), FDA announced that orally administered drug products containing levothyroxine sodium are new drugs and required manufacturers to have approved applications as a condition of marketing. The notice advised that manufacturers who were marketing levothyroxine sodium drug products on or before August 14, 1997, may continue to market their products until August 14, 2000.¹ The notice stated that a manufacturer who marketed a levothyroxine sodium drug product without an approved application after that date would be subject to regulatory action.

FDA permitted this period of continued marketing because it regards levothyroxine sodium products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. FDA has now concluded that manufacturers may need additional time to conduct studies and to prepare applications. Therefore, the agency extends by 1 year the compliance date given in the Federal Register notice of August 14, 1997, to permit continued marketing of these products until August 14, 2001.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505 (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Regulatory Affairs (21 CFR 5.20).

Dated: April 18, 2000.

Margaret M. Detzel,

Acting Associate Commissioner for Policy.
(FR Doc. 00-10322 Filed 4-25-00; 8:45 am)

BILLING CODE 4160-01-F

¹ After August 14, 1997, a new levothyroxine drug product may not be introduced into the market unless FDA has approved an application for that product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting is open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 19, 2000, 10 a.m. to 2 p.m.

Location: Holiday Inn, Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville MD, 301-827-7001, email: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation of the data and rationale for the regulatory action regarding the withdrawal from the U.S. market of Rezulin™ (troglitazone, Parke-Davis Pharmaceutical Research, a Division of Warner-Lambert) for the treatment of type 2 diabetes mellitus.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 15, 2000. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 15, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 17, 2000.

Linda A. Szydram,

Senior Associate Commissioner.

(FR Doc. 00-10321 Filed 4-25-00; 8:45 am)

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Loan Information System Records for the DHHS and DHUD Hospital Mortgage Insurance, Guarantee, and Direct Loan Programs (OMB 0915-0174)—EXTENSION

The Division of Facilities and Loans within the Health Resources and Services Administration monitors outstanding direct and guaranteed loans made under Section 621 of Title VI and Section 1601 of Title XVI of the Public Health Service Act, as well as loans insured under the Section 242 Hospital Mortgage Insurance Program of the National Housing Act. These programs were designed to aid construction and modernization of health care facilities by increasing the access of facilities to capital through the assumption of the mortgage credit risk by the Federal Government.

Operating statistics and financial information are collected annually from hospitals with mortgages that are insured under these programs. The information is used to monitor the financial stability of the hospitals to protect the Federal investment in these facilities. The form used for the data collection is the Hospital Facility Data Abstract. No changes in the form are proposed.

May 15, 2001

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

**RE: Labeling Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting a labeling amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000.

Draft labeling is being submitted for the package insert, container labeling (100 and 1000 count bottles), box label for the 100 and 1000 count bottles and the labeling for the blister packages (both commercial and physician's sample configurations)

This amendment consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 33070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)



Nancy Cafmeyer
Director, Regulatory Affairs

JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
St. Louis, Missouri 63146
314 576-6100 Fax 314 469-5749
www.jmedpharma.com

May 2, 2001



NDA ORIG AMENDMENT
N-000-BC

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

**RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The information submitted in this amendment was requested by the Dr. David Lewis, FDA Chemistry Reviewer, as a result of teleconferences held between Dr. Lewis and Jones on March 15 and 22, 2001.

Dr. Lewis requested updated stability data from the 15 month test interval for selected batches and packaging sizes of Levoxyl. An amendment was submitted on April 6, 2001 that contained the available requested stability data. We also committed to submit the remaining data when the analyses were completed. The updated stability data from the three outstanding batches is presented in Attachment 1.

This amendment consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. Additionally desk copies are being sent to Mr. Steve McCort (Project Manager, FDA) and Dr. David Lewis (FDA Chemistry Reviewer).

By this letter, it is certified that a true copy of the amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the application filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

Levoxyl (Levothyroxine Sodium Tablets, USP)

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 33070.

Sincerely,

JONES PHARMA INCORPORATED

(A wholly owned subsidiary of King Pharmaceuticals, Inc.)



Nancy Cafmeyer

Director, Regulatory Affairs

APPEARS THIS WAY
ON ORIGINAL



ORIGINAL

JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
St. Louis, Missouri 63146
314 576-6100 Fax 314 469-5749
www.jmedpharma.com

April 6, 2001



ORIG AMENDMENT
N-000-BC

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The information submitted in this amendment was requested by the Dr. David Lewis, FDA Chemistry Reviewer, as a result of teleconferences held between Dr. Lewis and Jones on March 15 and 22, 2001.

Dr. Lewis requested updated stability data from the 15 month test interval for selected batches and packaging sizes of Levoxyl. The requested updated stability data is presented in Attachments 1-3. Dr. Lewis also requested that Jones calculate the projected loss in potency for the 18, 21 and 24 month test intervals for each stability bracket and packaging size of Levoxyl submitted in NDA 21-301. The projection data is presented in Attachments 4-6.

This amendment consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. Additionally desk copies are being sent to Mr. Steve McCort (Project Manager, FDA) and Dr. David Lewis (FDA Chemistry Reviewer).

By this letter, it is certified that a true copy of the amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the application filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

**Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)

Nancy Cafmeyer

Nancy Cafmeyer
Director, Regulatory Affairs

REVIEWS COMPLETED	
CSO ACTION:	
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CSO INITIALS	DATE



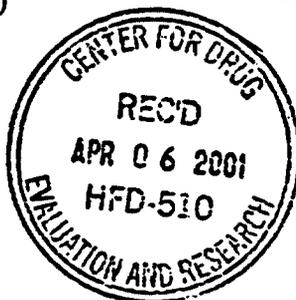
JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
St. Louis, Missouri 63146
314 576-6100 Fax 314 469-5749
www.jmedpharma.com

April 5, 2001

FEDERAL EXPRESS

Dr. Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Regulatory Control Room 14B-19
Food and Drug Administration
100 Fishers Lane
Rockville, MD 20857

N 000 BB
NDA ORIG AMENDMENT



Re: **Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The information submitted in this amendment was requested by the FDA Biopharmaceutics Reviewers, as a result of a teleconference held between FDA and Jones on April 3, 2001.

The FDA Biopharmaceutics Reviewers requested that Jones perform dissolution testing to determine the stability of the test solution in the vial hourly for up to 10 hours with and without SLS in the medium. The data from this requested testing are provided as Attachment 1.

This application consists of a single volume. An archival copy is being filed in a blue folder and a regulatory review copy is being filed in a red folder. Additionally desk copies are being sent to Steve McCort (Project Manager, FDA) and Dr. Steve Johnson (FDA Biopharmaceutics Reviewer).

In this letter, it is certified that a true copy of this amendment (including a copy of FDA application number 356h and a certification that the contents are a true copy of the amendment filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. A "field copy" was contained in a burgundy folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,
JONES PHARMA INCORPORATED
wholly owned subsidiary of King Pharmaceuticals, Inc.)

Tracy Cafmeyer

Tracy Cafmeyer
Director, Regulatory Affairs

BEST POSSIBLE COPY

REVIEWS COMPLETED
CSO ACTION:
<input type="checkbox"/> LETTER <input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS _____ DATE _____



ORIGINAL

JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
St. Louis, Missouri 63146
314 576-6100 Fax 314 469-5749
www.jmedpharma.com

March 14, 2001



VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

BB
NDA ORIG AMENDMENT

**RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The information submitted in this amendment was requested by the FDA Biopharmaceutics Reviewers, as a result of a teleconference held between FDA and Jones on February 9, 2001.

Dissolution profiles from three lots of each strength were submitted in Section 6.3 of the original NDA. The procedure utilized for the dissolution tests followed the USP 24 monograph which included 0.2% sodium lauryl sulfate (SLS) in the dissolution medium. The FDA Biopharmaceutics Reviewers requested that Jones perform dissolution testing without the SLS in the medium to determine if the SLS is a necessary component. The data from this requested testing are provided as Attachment 1. It was agreed that if removing the SLS did not produce acceptable results, we did not need to proceed with further testing.

This application consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. Additionally desk copies are being sent to Mr. Steve McCort (Project Manager, FDA) and Dr. Steve Johnson (FDA Biopharmaceutics Reviewer).

**Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

By this letter, it is certified that a true copy of this amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the amendment filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)

Nancy Cafmeyer

Nancy Cafmeyer
Director, Regulatory Affairs

Enclosure

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

APPEARS THIS WAY
ON ORIGINAL



ORIGINAL

AVEN



JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
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March 8, 2001

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

N 000 L
NEW CORRESP

RE: General Correspondence to NDA 21-301
Levoxyl (levothyroxine sodium tablets, USP)

np/sgd
3-19-1

Reference is made to our New Drug Application for Levoxyl (Levothyroxine Sodium Tablets, USP), NDA 21-301 and to IND _____

On March 8, 2001 an amendment was submitted to IND _____ clarifying that responsibility for sample retention has been retained by Jones Pharma (Attachment 1). Retention samples for the studies conducted in support of NDA 21-301 are being properly stored at our company subsidiary JMI-Daniels Pharmaceuticals, Inc., 2540 26th Ave. N., St. Petersburg, Florida 33713.

If there are any questions concerning this matter or further clarification is required, please do not hesitate to contact me by telephone at (314) 576-6100 or by fax at (314) 205-9497.

Sincerely,

JONES PHARMA INCORPORATED
(A subsidiary of King Pharmaceuticals, Inc.)

Nancy Cafmeyer

Nancy Cafmeyer
Director, Regulatory Affairs

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

Memo
4-15-97 9:00
2-12-00
NC



DUPLICATE



JONES PHARMA INCORPORATED
1945 Craig Road, P.O. Box 46903
St. Louis, Missouri 63146
314 576-6100 Fax 314 469-5749
www.jmedpharma.com

February 27, 2001

VIA FEDERAL EXPRESS

John Jenkins, M.D. Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-510)
Document Control Room 14B-19
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

N 000 BZ
NDA ORIG AMENDMENT

**RE: Amendment to NDA 21-301
Levoxyl (Levothyroxine Sodium Tablets, USP)**

Dear Dr. Jenkins:

JONES PHARMA INCORPORATED is hereby submitting an amendment to our pending New Drug Application (NDA) for Levoxyl (Levothyroxine Sodium Tablets, USP) submitted July 28, 2000. The purpose of this amendment is to provide updated stability data.

This amendment consists of a single volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder.

By this letter, it is certified that a true copy of the amendment (including a copy of FDA application form 356h and a certification that the contents are a true copy of the application filed with the Center for Drug Evaluation and Research) was sent to the Kansas City District office of the FDA. This "field copy" was contained in a burgundy folder.

We look forward to the approval of this NDA. Should any additional information be required, please do not hesitate to contact me at (314) 576-6100 ext. 3070.

Sincerely,

JONES PHARMA INCORPORATED
(A wholly owned subsidiary of King Pharmaceuticals, Inc.)

Nancy Cafmeyer

Nancy Cafmeyer
Director, Regulatory Affairs