

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**SPECIAL INTEREST TOPIC**

**TITLE: DILANTIN INJECTION RECALLS**  
**D005-6 AND D232-5**

**WARNER LAMBERT COMPANY**

Dilantin 100 mg (Part 2)  
Lot No. 00815P  
Parke-Davis/W-L  
Rochester, MI

D-000376

Parke-Davis Div. of Warner-Lambert  
Rochester

Dilantin 100 mg

Lot No. 00815P

Recall No. D-005-6

TERMINATED 01/09/90

SD  
1/14/97

Wed Oct 11, 1995 3:26 pm EST

DET-DO FDA / MCI ID: 611-5836

\* CDER-COM-10 FDA / MCI ID: 621-9259

ORA-DEEO FDA / MCI ID: 626-8941

PRESS-PKLN FDA / MCI ID: 632-3149

PRESS-WASH FDA / MCI ID: 622-9289

CHI-FO FDA / MCI ID: 633-3111

DET-DO FDA / MCI ID: 611-5836

Subject: PARKE-DAVIS RECALL RECOMMENDATION

DATE: OCTOBER 11, 1995

TO: ROCKVILLE/CDER/OC/RECALL STAFF/HFD-300

ATTN: GUST KOUSTENIS

FROM: DET-DO/JUDITH A. JANKOWSKI, R & E COORDINATOR/HFR-MW295

CC: ROCKVILLE/ORA/DEEO/EMERG OPN BRANCH/HFC-162

ROCKVILLE/ACPA/FDA PRESS OFFICE/HFI-20

WASHINGTON/ACPA/FDA ENFORCEMENT REPORT STAFF/HFI-21

CHI-FO/RFDD/HFR-MW1

DET-DO/DIB/HFR-MW250

SUBJECT: RECOMMENDATION FOR HEALTH HAZARD EVALUATION AND RECALL  
NUMBER \*\* (EXTENSION OF RECALL D-232-5) \*\*

RECOMMENDATION FOR FIRM-INITIATED RECALL

CODE: 56002

PRODUCT CODE: 61MCP24

1818977

DISTRICT: 9 (Detroit)

REASON: Complaints of discolored product

CURRENT STATUS: On-going

PRODUCTS UNDER RECALL:

Parke-Davis brand Phenytoin Sodium Injection 100 mg in 2 mL,

Product

This product is supplied as a package containing ten 2 mL

D-005-6

Date: Wed Oct 11, 1995 3:26 pm EST  
From: DET-DO FDA / MCI ID: 611-5836

TO: CDER-COM-IO FDA / MCI ID: 621-9259  
TO: ORA-DEEO FDA / MCI ID: 626-8941  
TO: PRESS-PKLN FDA / MCI ID: 632-3149  
TO: PRESS-WASH FDA / MCI ID: 622-9289  
TO: CHI-FO FDA / MCI ID: 633-3111  
TO: \* DET-DO FDA / MCI ID: 611-5836  
Subject: PARKE-DAVIS RECALL RECOMMENDATION

DATE: OCTOBER 11, 1995

TO: ROCKVILLE/CDER/OC/RECALL STAFF/HFD-300  
ATTN: GUST KOUSTENIS

FROM: DET-DO/JUDITH A. JANKOWSKI, R & E COORDINATOR/HFR-MW295

INFO: ROCKVILLE/ORA/DEEO/EMERG OPN BRANCH/HFC-162  
ROCKVILLE/ACPA/FDA PRESS OFFICE/HFI-20  
WASHINGTON/ACPA/FDA ENFORCEMENT REPORT STAFF/HFI-21  
CHI-FO/RFDD/HFR-MW1  
DET-DO/DIB/HFR-MW250

SUBJECT: RECOMMENDATION FOR HEALTH HAZARD EVALUATION AND RECALL  
NUMBER \* \* (EXTENSION OF RECALL D-232-5) \* \*

-----  
RECOMMENDATION FOR FIRM-INITIATED RECALL

PAC CODE: 56002  
PRODUCT CODE: 61MCP24  
CFN: 1818977  
DISTRICT: 9 (Detroit)  
REASON: Complaints of discolored product  
RECALL STATUS: On-going

1) PRODUCTS UNDER RECALL:

Dilantin brand Phenytoin Sodium Injection 100 mg in 2 mL,  
USP

The product is supplied as a package containing ten-2 mL  
steri-dose syringes.

2) CODE:

Lot No. 00815P, N 0071-4488-47, expiration date, 11/96

3) RECALLING FIRM/MANUFACTURER:

Recalling Firm: The Parke-Davis Division of

Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950

Manufacturer: Warner-Lambert Company  
Parke-Davis  
Sterile Products Division  
870 Parkdale Road  
Rochester, MI 48307

4) REASON FOR RECALL RECOMMENDATION:

Investigation triggered by a customer complaint about discolored product revealed that part of lot 00815P had been manufactured using incorrect stoppers. The discoloration was probably caused by the use of #845 gray stoppers instead of #1816 gray stoppers which are approved for the product. Further investigation showed that no discolored syringes were found in any stability or reserve samples for 1994 and 1995 other than lot 00515P which was previously recalled to the dispensing level (D-232-5). Review of lot 00815P three month stability studies indicate all results including assay were within specification.

The firm has not determined the exact nature and etiology of the clear yellow discoloration at this time. The firm feels the discoloration appears to be related to the process causing yellow discoloration referred to in the prescribing information for the product. The labeling for Parenteral Dilantin states, "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit...The solution is suitable for use as long as it remains free of haziness and precipitate. Upon refrigeration or freezing, a precipitate might form; this will dissolve again after the solution is allowed to stand at room temperature. The product is still suitable for use. Only a clear solution should be used. The faint yellow coloration may develop; however, this has no effect on the potency of the solution." This statement in the labeling informs the health care provider that parenteral Dilantin solution is suitable for use regardless of the presence of a faint clear yellow coloration.

The firm feels two additional considerations are relevant. This is that stopper #845 is approved for use as part of the container system for other parenteral solutions and a teflon faced #845 stopper previously was utilized in the manufacturer of Parenteral Dilantin supplied in sterile disposable syringes.

The firm concludes that based on the approved use of the #845 stopper in other parenteral solutions, the previous use of teflon faced #845 stoppers in the manufacture of

Parenteral Dilantin, the information on clear yellow discoloration in the product's labeling, and the stability profile of this lot of Dilantin, the probability of serious adverse health consequences from exposure to Parenteral Dilantin, lot 00815P, is remote.

5) VOLUME OF PRODUCT IN COMMERCE:

A total of 15,416 packages was released for distribution from the firm's Elk Grove, IL and Lititz, PA distribution centers (DC). At the time of the recall there was no product remaining at the Lititz DC. Product remaining at the Elk Grove DC (86 units) was placed under quarantine. The quantity returned will be documented at the completion of the recall.

DC	QTY	REL DATE	SHIP START	SHIP END
Elk Gr.	7120	02/22/95	03/24/95	07/28/95
Lititz	8296	02/22/95	02/23/95	06/08/95

6) DISTRIBUTION PATTERN:

The recall was directed to the dispensing level.

The lot was distributed to direct accounts, primarily drug wholesale distributors. Four foreign accounts were involved. A breakdown of consignees is as follows:

Designation	Number of Accounts
Free Goods Account	
Wholesalers	
Physician Supplier	
Proprietary Hospital	
Non-Profit Hospital	
HMO with Hospital	
Clinics/Physicians	
Federal Government Facility	
V.A. Facility	
Military Facility	
Federally Funded Facility	
City Facility	
Buying Group	
Total	

Foreign Accounts:

Gov. of the Virgin Islands  
 Department of Health  
 St. Thomas Hospital Pharmacy  
 48 Sugar Estate  
 St. Thomas, Virgin Islands

A.S. Bryden & Sons, Ltd.  
 33 Independence Square  
 Port of Spain  
 Trinidad

DET-DO obtained recall information from the firm's headquarters in Morris Plains, NJ. On-site inspection at the Rochester facility was not conducted at this time, however, the situation may be covered during an upcoming scheduled inspection.

DET-DO will monitor the firm's recall to completion. Recommend Level E (None) FDA audit checks based on firm's history of conducting effective recalls.

Photocopy of firm correspondence detailing recall was sent to HFD-300 on 10/12/95.

10) RECOMMENDING OFFICIAL: Judith A. Jankowski, R & E  
Coordinator, DET-DO

CONCURRENCE: Brenda J. Holman, District Director, DET-DO



Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260  
FAX: 313-226-3076

January 9, 1996

Ms. Uma Iyer, Senior Manager  
Quality Compliance  
Parke-Davis Division  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950

RE: Recall # D-232-5  
D-005-6

Dear Ms. Iyer:

The Food and Drug Administration has completed the audits of your firm's actions concerning:


Recall Number D-232-5; Dilantin 100 mg/2 mL Injection, lot 00515P  
Recall Number D-005-6; Dilantin 100 mg/2 mL Injection, lot 00815P

The products were recalled because of discoloration.

We conclude that the recalls have been completed and there has been proper disposition of the recalled products. Therefore, FDA considers the recalls terminated.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Food, Drug and Cosmetic Act in the future.

Sincerely yours,

  
Brenda J. Holman  
District Director  
Detroit District

cc: Recall File # D-232-5  
D-005-6

EF

BJH:SW:bjm



Date: January 9, 1996  
From: Sandra Williams, Compliance Officer  
Subject: Recall Termination Recommendation, Class III  
Firm Initiated Recall No. D-005-6  
To: CDER, Office of Compliance, Recall Section, HFD-300

Recalling Firm: Parke-Davis division  
Warner-Lambert Company  
Morris Plains, NJ

Manufacturer: Warner-Lambert Company  
Parke-Davis Sterile Products Division  
870 Parkdale Rd.  
Rochester, MI. 48307

Section I - Recall Data

1. Recall Number: D-005-6
2. Product: Dilantin 100 mg/2 mL Injection, lot 00815P.
3. Quantity of product recovered: 35,962 syringes.
4. Disposition of returned product and held stock: As of December 1995, all stocks of this product had been removed to the firm's contract disposal company and, thus, there is no possibility of reshipment of product.
5. Samples collected: none
6. Date recall completed: January 2, 1996

Section II - Verification of Effectiveness By Firm

7. Date and method of notification and number of consignees notified of the recall: Recall notifications were sent on 8/11/95 to [REDACTED] dispensing level accounts via certified mail, return receipt requested.
8. Number of consignees responding to the recall communication: [REDACTED] of the [REDACTED] accounts responded to the recall by filling out the business reply cards. Of these, [REDACTED] customers indicated having a total of twenty eight thousand two hundred and seven (28,207) syringes on hand. There were [REDACTED] non-responders (i.e., no business reply cards) to the recall. Of these, [REDACTED] accounts returned product bringing down the number of non-responders

to [REDACTED]). Of these [REDACTED] non-responders, all but [REDACTED] accounts received the recall notification as verified by proof of delivery. The percentage of responders and non-responders to the recall are [REDACTED] and [REDACTED], respectively.

9. Number, type, and results of effectiveness checks made: Effectiveness check questionnaires were sent to seven (7) accounts via certified mail, return receipt requested. All seven responded to the questionnaire. Two accounts could not remember if they had received any of the recalled lot. Both accounts did indeed receive the lot and had returned product in response to the recall notification.
10. Further information pertinent to the evaluation of the effectiveness of the firm's recall: none


#### Section III - Results of FDA Audit Checks

11. Number of audit checks; how conducted: None
12. Breakdown of audit check results: n/a
13. Delays encountered in firm's recall: n/a

#### Section IV - Analysis of Recall

14. Nature of violation/problem: Complaints of discolored product. The firm had used an incorrect stopper, in that a #845 gray stopper was used instead of a #1816 gray stopper. The #845 gray stopper was approved for use on other parenteral solutions, teflon-faced #845 stoppers had been previously used by the firm, and the product's labeling discusses the possibility of discolored product and provides instructions should it be found.
15. Action firm has taken to prevent similar occurrences: The stopper supplier was audited in May 1995 and there are no outstanding issues.
16. District follow-up conducted: None.
17. District review of total effort: effective
18. Legal action: none

Recommended/Prepared by: \_\_\_\_\_

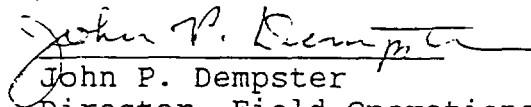
  
Sandra Williams  
Compliance Officer  
Detroit District Office

  
Date

Concur: ✓

Disapprove: \_\_\_\_\_

Date: 1/9/96



John P. Dempster  
Director, Field Operations Branch  
Detroit District Office

Orig:HFD-300  
cc:HFC-162  
HFA-224  
Recall file (D-005-6)  
EF  
Kal R/P  
GR R/P

**PARKE-DAVIS**  
People Who Care

January 2, 1995

Ms. Judith A. Jankowski  
Recall and Emergency Coordinator  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

Re: Recall of Dilantin 100 mg/2 mL Injection, D-005-6

Dear Ms. Jankowski,

The Parke-Davis division of Warner-Lambert Company initiated a recall for lot 00815P of Dilantin Injection on August 11, 1995. The information presented below is in response to your letter dated November 20, 1995 on the recall.

**1. Number of consignees notified of the recall, and date and method of notification.**

Recall notifications, dated 8/11/95, were sent on 8/11/95 to [REDACTED] dispensing level accounts via certified mail, return receipt requested.

**2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.**

[REDACTED] of the [REDACTED] accounts responded to the recall by filling out the business reply cards. Of these, [REDACTED] customers indicated having a total of twenty eight thousand two hundred and seven (28,207) syringes on hand.

**3. Number of consignees that did not respond.**

There were [REDACTED] non-responders (i.e., no business reply cards) to the recall. Of these, [REDACTED] accounts returned product bringing down the number of non-responders to [REDACTED]. Of these [REDACTED] non-responders, all but [REDACTED] accounts received the recall notification as verified by proof of delivery. The percentage of responders and non-responders to the recall are [REDACTED] and [REDACTED] respectively. The number of non-responders is sorted by trade class in Table I below:

Ms. Judith A. Jankowski  
 January 2, 1995  
 Dilantin 100 mg/2 mL Injection

Table I - Non-responders grouped by Trade Class

Trade Class	Designation	Number of non-responders
[REDACTED]	Free Goods Account	[REDACTED]
	Wholesalers	[REDACTED]
	Physician Supplier	[REDACTED]
	Non-Profit Hospital	[REDACTED]
	HMO with Hospital	[REDACTED]
	Federal Government Facility	[REDACTED]
	V.A. Facility	[REDACTED]
	Military Facility	[REDACTED]
	Federally Funded Facility	[REDACTED]
	City Facility	[REDACTED]
Buying Group	[REDACTED]	

4. Number of products returned or corrected by each consignee contacted and the quantity of product accounted for.

Product returns are listed in Table II below.

Table II - Product Returned

Account #	Customer Name	Quantity*
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CCI

Ms. Judith A. Jankowski  
January 2, 1995  
Dilantin 100 mg/2 mL Injection

Table II Contd. - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

CCI

Ms. Judith A. Jankowski  
January 2, 1995  
Dilantin 100 mg/2 mL Injection

Table II Contd. - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

~~CCI~~

Total Quantity\* ..... 35962

\* Quantity refers to number of syringes

Ms. Judith A. Jankowski  
January 2, 1995  
Dilantin 100 mg/2 mL Injection

5. Number and results of effectiveness checks that were made and method in which conducted.

Per your letter of 11/20/95, a level D effectiveness check was conducted. Effectiveness check questionnaires were sent to seven (7) accounts via certified mail, return receipt requested. All seven responded to the questionnaire. Two accounts, [REDACTED], and [REDACTED] could not remember if they had received any of the recalled lot. Both accounts received the lot and had returned product in response to the recall notification.

6. Estimated time frame for completion of recall.

It is our determination that we have taken the recall for Dilantin Injection to completion. At this time we request your permission to destroy the material and close out the recall.

7. Corrective action taken to prevent similar problems in future.

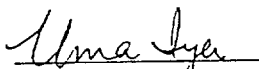
The stopper supplier was audited in May 1995 and there are no outstanding issues.

Summary:

Recall for Dilantin Injection lot 00815P was initiated to the secondary level on August 11, 1995. The response rate to the recall was [REDACTED]%. Level D effectiveness check was completed. Permission to destroy the recalled material is requested.

I trust this completes the information on the recall of Dilantin Injection. Please call me at (201) 540-6528 if you have any questions in this matter.

Sincerely,

  
Uma Iyer

Sr. Manager  
Quality Compliance

copies:

C. Blewett L. Calitri L. Dell D. Krajewski R. Sheroff

*Per Ms. Iyer,  
product has been moved  
to contractor for disposal.  
1/5/96  
SW*



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260  
FAX: 313-226-3076

November 20, 1995

Leonard A. Dell, Vice President  
Pharmaceutical Quality Operations  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950

Re: Recall # D-005-6

Dear Mr. Dell:

We agree with your firm's decision to recall Dilantin brand Phenytoin Sodium Injection, 100 mg in 2 ml, U.S.P.; lot 00815P, expiration 11/96, because of complaints of discolored product.

We have reviewed your action and conclude that it meets the formal definition of a "Recall". This is significant, as your action is an alternative to a Food and Drug Administration legal action to remove your defective product from the market. This recall will be reported in an upcoming issue of the FDA Weekly Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) - Guidelines on Policy, Procedures and Industry Responsibilities" issued June 16, 1978 in conducting your recall. Enclosed you will find a copy of this "Enforcement Policy" as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks".

This recall has been classified by the FDA as a Class III recall. This means use of the violative product does not present a significant risk of serious adverse health consequences.

Our evaluation indicates that this recall should be conducted to the dispensing level and that level D effectiveness checks should be conducted by your firm. Level D effectiveness checks means that your firm should make follow-up contacts at 2% of your direct consignees to confirm that they were notified and that they followed your firm's recall instructions.

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We therefore urge you to immediately begin making plans to destroy the product or recondition it to bring it into compliance with the law. Either method should be done under the supervision of an investigator from this office. Our Detroit District office should be notified prior to the initiation of reconditioning or destruction of the recalled product.

We request that you advise us within ten days of the steps you have taken to insure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your method of disposition of the returned goods.

In addition, we request that you submit to our Detroit District office a recall status report at monthly intervals until your recall is completed. This recall status report should contain the following information:

- (1) Number of consignees notified of the recall, and date and method of notification.
- (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- (3) Number of consignees that did not respond.
- (4) Quantity of product on hand at your firm when recall initiated.
- (5) Quantity of product returned by consignees and the quantity of product accounted for.
- (6) Number, method of conducting, and results of effectiveness checks that were made.
- (7) Estimated time frames for completion of the recall.
- (8) What corrective action have you taken to prevent the occurrence of similar problems in the future?

Page 3

Leonard A. Dell, V.P., Warner-Lambert Co.,  
Morris Plains, NJ, Recall # D-005-6

This status report and your response to this letter should be addressed to: Food and Drug Administration, 1560 East Jefferson, Detroit, Michigan 48207, Attention: Judith A. Jankowski, Recall Coordinator.

Our judgment regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product in commerce or other legal sanctions under the Food, Drug and Cosmetic Act.

Your cooperation in this matter is important for the protection of the general public.

Sincerely yours,



Brenda J. Holman  
District Director  
Detroit District



August 24, 1995

Ms. Judith A. Jankowski  
Recall and Emergency Coordinator  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

**Re: Recall of Dilantin® Injection**

Dear Ms. Jankowski,

Enclosed please find the follow-up information pertaining to the recall of Dilantin® Injection initiated by our firm on August 11, 1995. I have answered the questions in the same order as they appear in the recall questionnaire.

**1. Product:**

Dilantin® 100 mg in 2 mL  
Phenytoin Sodium Injection, USP

**2. Code:**

Lot 00815P, N 0071-4488-47, expiration date, 11/96. The product is supplied as a package containing ten-2 mL steri-dose® syringes. The lot was shipped to our Elk-Grove (Illinois) and Lititz (Pennsylvania) customer service centers for distribution.

**3. Recalling Firm/Manufacturer:**

The recall was initiated by:

The Parke-Davis Division of Warner-Lambert Co.  
182 Tabor Road  
Morris Plains, NJ 07950

Judith A. Jankowski  
 FDA, Detroit District Office  
 Dilantin® Injection Recall Questionnaire - August 24, 1995

The recalled product was manufactured at the Warner-Lambert Co. facility located at the following address:

Warner-Lambert Company  
 Parke-Davis  
 Sterile Products Division  
 870 Parkdale Road  
 Rochester, MI 48307

**4. Reason for Recall:**

Investigation triggered by a customer complaint about discolored product revealed that a part of lot 00815P had been manufactured using incorrect stoppers. The discoloration was probably caused by the use of '845' gray stoppers instead of the '1816' gray stoppers which are approved for the product.

**Health Hazard Evaluation:**

See Attachment I.

**5. Volume of Product in Commerce:**

A total of 15,416 units was released for distribution. Out of this amount, 7120 units went to the Elk Grove and the remaining 8296 units to the Lititz distribution centers (DC). The table below gives the quantity of product remaining, transaction dates, and quantity shipped from the DCs. Upon initiation of the recall, the product remaining at Elk Grove was placed under quarantine. Product returns will be documented at the completion of the recall.

DC	Quantity - Total		Receival Date	Shipping Start Date	Shipping End Date
	Remaining	Shipped			
Elk Grove	86	7034	02/22/95	03/24/95	7/28/95 <sup>a</sup>
Lititz	--	12,133 <sup>b</sup>	02/22/95	02/23/95	06/08/95

<sup>a</sup> Date remaining stock was placed under quarantine.

<sup>b</sup> A diversion of 3840 inventory units from the Elk Grove distribution center accounts for the excess activity at Lititz.

Judith A. Jankowski  
FDA, Detroit District Office  
Dilantin® Injection Recall Questionnaire - August 24, 1995

**6. Distribution Pattern:**

The recall was directed to the dispensing level. The information pertaining to the distribution pattern is provided in Attachment II.

Attachment II-a gives the list of accounts in zip code sequence. The list of government accounts is provided in Attachment II-b and the summary report for the distribution pattern is found in Attachment II-c. Six identical duplicate accounts (*see* Attachment II-d) were deleted from the zip code sequence list. Attachment II-e contains numerical code designations for trade classes and the number of accounts in each trade class after elimination of the six duplicates shown in Attachment II-d. The direct account list contained four foreign accounts, two of whom were from Jamaica (0730900000 and 0884400000), one from Virgin Islands (0488100000), and one from Trinidad (0709500000).

**7. Firm's Recall Strategy:**

The direct accounts were notified of the recall on August 11, 1995 via certified mail, return receipt requested. In the recall letter, we instructed our accounts to examine their inventory to determine if they had any of the referenced lot in stock. If so, we requested that they discontinue dispensing the lot and promptly return it to Parke-Davis. We also asked our accounts that if they had further distributed to other accounts they should conduct a sub-recall for the lot.

In the past, we have improved the response rate to our recalls by sending a second recall notification, or, by contacting where feasible, the non-respondents by phone. At the close of the recall, the recalled product will be destroyed by incineration. Destruction will be carried out after obtaining approval from the FDA.

**8. Firm's Official:**

All official correspondence connected with the recall should be directed to:

Leonard A. Dell  
Vice President, Pharmaceutical Quality Operations  
Warner-Lambert Co.  
182 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-6091  
Fax: (201) 631-7722

Judith A. Jankowski  
FDA, Detroit District Office  
Dilantin® Injection Recall Questionnaire - August 24, 1995

Media inquiries should be directed to:

Ms. Jennifer Mann  
Corporate Public Affairs  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-4268

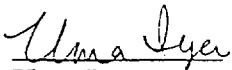
**Additional Product Information:**

Three sets of syringe labels, inserts, and cartons are included in Attachment III.

Three samples of the recall package including the letter, business reply card, and shipping label for product return are included in Attachment IV.

This concludes the response to the recall questionnaire. In addition to the hard copy, I have sent you this report, electronically, without the attachments found in I, II-a, II-b, II-c, III, and IV, to the address: JJANKOWS@FDAEM.SSW.DHHS.GOV@PMDF@IN. If you have any questions with respect to this recall, you can reach me either by phone at (201) 540-6528 or by fax at (201) 631-7722.

Sincerely,

  
Uma Iyer  
Senior Manager  
Quality Compliance

copies:

C. Blewett  
C. Curtin  
L. Dell  
D. Krajewski  
R. Sheroff

**Memorandum**

To: Of Record

Date: Aug 9, 1995

From: Bruce A. Boselli, M.D. <sup>5/20</sup>

Subject: Medical Opinion - Parenteral Dilantin (Phenytoin Sodium Injection, USP) Lot# 00815P

Certain syringes from Parenteral Dilantin (Phenytoin Sodium Injection, USP) lot# 00815P supplied in sterile disposable syringes were manufactured with stopper 845 rather than stopper 1816. Dilantin (Phenytoin Sodium Injection, USP) contained in syringes manufactured with stopper 845 appear to be associated with a clear yellow discoloration of the parenteral phenytoin solution. Review of lot 00815P three month stability studies indicate all results including assay were within specification.

The exact nature and etiology of the clear yellow discoloration have not been established at this time. The discoloration appears to be related to the process causing yellow discoloration referred to in the prescribing information for the product. The labeling for Parenteral Dilantin (Phenytoin Sodium Injection, USP) states "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. . . . The solution is suitable for use as long as it remains free of haziness and precipitate. Upon refrigeration or freezing, a precipitate might form; this will dissolve again after the solution is allowed to stand at room temperature. The product is still suitable for use. Only a clear solution should be used. A faint yellow coloration may develop; however, this has no effect on the potency of the solution." This statement in the labeling informs the health care provider that parenteral Dilantin solution is suitable for use regardless of the presence of a faint clear yellow coloration.

Two additional considerations relevant to this opinion are stopper 845 is approved for use as part of the container system for other parenteral solutions and a Teflon faced 845 stopper previously was utilized in the manufacture of Parenteral Dilantin (Phenytoin Sodium Injection, USP) supplied in sterile disposable syringes.

Therefore, based on the approved use of the 845 stopper in other parenteral solutions, the previous use of Teflon faced 845 stoppers in the manufacture of Parenteral Dilantin (Phenytoin Sodium Injection, USP), the information on clear yellow discoloration in the product's labeling, and the stability profile of this lot of Dilantin the probability of serious adverse health consequences from exposure to Parenteral Dilantin (Phenytoin Sodium Injection, USP) lot 00815P is remote.



Dilantin (Phenytoin Sodium) Inj USP  
Lot No. 00515P  
Parke-Davis/Warner-Lambert Rochester, MI

D-232-5

Parke-Davis Div. Warner-Lambert Rochester, N

Dilantin (Phenytoin Sodium Inj) USP

Lot No. 00515P

Recall No. D-232-5

TERMINATED

1/17/96

pd  
1/14/97

ate: Mon Aug 07, 1995 3:59 pm EST  
rom: DET-DO FDA / MCI ID: 611-5836

O: \* CDER-COM-IO FDA / MCI ID: 621-9259  
O: ORA-DEEO FDA / MCI ID: 626-8941  
O: PRESS-PKLN FDA / MCI ID: 632-3149  
O: PRESS-WASH FDA / MCI ID: 622-9289  
O: CHI-FO FDA / MCI ID: 633-3111  
O: DET-DO FDA / MCI ID: 611-5836  
Subject: PARKE-DAVIS DILANTIN RECALL RECOMMENDATION

DATE: AUGUST 4, 1995

TO: ROCKVILLE/CDER/OC/RECALL STAFF/HFD-300  
ATTN: GUST KOUSTENIS

FROM: DET-DO/JUDITH A. JANKOWSKI, R & E COORDINATOR/HFR-MW295

INFO: ROCKVILLE/ORA/DEEO/EMERG OPN BRANCH/HFC-162  
ROCKVILLE/ACPA/FDA PRESS OFFICE/HFI-20  
WASHINGTON/ACPA/FDA ENFORCEMENT REPORT STAFF/HFI-21  
CHI-FO/RFDD/HFR-MW1  
DET-DO/DIB/HFR-MW250

SUBJECT: ALERT TO RECALL SITUATION AND RECOMMENDATION FOR HEALTH  
HAZARD EVALUATION AND RECALL NUMBER

RECOMMENDATION FOR FIRM-INITIATED RECALL

AC CODE: 56002  
PRODUCT CODE: 61MCP24  
N: 1818977  
DISTRICT: 9 (Detroit)  
REASON: Complaints of discolored product  
RECALL STATUS: On-going

D-232-5

PRODUCTS UNDER RECALL:

Dilantin brand Phenytoin Sodium Injection 100 mg in 2 mL,  
USP

The product is supplied as a package containing ten-2 mL  
steri-dose syringes. The lot was shipped to our Elk-Grove  
(Illinois) and Lititz (Pennsylvania) customer service  
centers for distribution.

CODE:

Lot No. 00515P, N 0071-4488-47, exp date, 11/96

DATE: AUGUST 9, 1995  
TO: FINOR/HFC-162  
FROM: DET-DO/JUDITH A. JANKOWSKI, R & E COORDINATOR/HFR-MW295  
SUBJECT: INITIAL NOTIFICATION OF CLASS III  
FIRM INITIATED RECALL/FDA AUDIT CHECK LEVEL E

-----

RECALL NUMBER: D-232-5  
PAC CODE: 56002  
PRODUCT CODE: 61MCP24  
CFN: 1818977  
DISTRICT: 9 (Detroit)  
REASON: Complaints of discolored product  
RECALL STATUS: On-going

1) PRODUCTS UNDER RECALL:

Dilantin brand Phenytoin Sodium Injection 100 mg in 2 mL,  
USP

The product is supplied as a package containing ten-2 mL  
steri-dose syringes. The lot was shipped to our Elk- Grove  
(Illinois) and Lititz (Pennsylvania) customer service  
centers for distribution.

2) CODE:

Lot No. 00515P, N 0071-4488-47, exp date, 11/96

3) RECALLING FIRM/MANUFACTURER:

Recalling Firm: The Parke-Davis Division of  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950

Manufacturer: Warner-Lambert Company  
Parke-Davis  
Sterile Products Division  
870 Parkdale Road  
Rochester, MI 48307

4) REASON FOR RECALL RECOMMENDATION:

Investigation triggered by a customer complaint about  
discolored product revealed that part of lot 00515P had been  
manufactured using incorrect stoppers. The discoloration  
was probably caused by the use of #845 gray stoppers instead

of #1816 gray stoppers which are approved for the product. Further investigation showed that no discolored syringes were found in any stability or reserve samples for 1994 and 1995 other than lot 00515P which was recalled to the dispensing level.

The firm has not determined the exact nature and etiology of the clear yellow discoloration at this time. The firm feels the discoloration appears to be related to the process causing yellow discoloration referred to in the prescribing information for the product. The labeling for Parenteral Dilantin states, "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit...The solution is suitable for use as long as it remains free of haziness and precipitate. Upon refrigeration or freezing, a precipitate might form; this will dissolve again after the solution is allowed to stand at room temperature. The product is still suitable for use. Only a clear solution should be used. The faint yellow coloration may develop; however, this has no effect on the potency of the solution." This statement in the labeling informs the health care provider that parenteral Dilantin solution is suitable for use regardless of the presence of a faint clear yellow coloration.

The firm feels two additional considerations are relevant. This is that stopper #845 is approved for use as part of the container system for other parenteral solutions and a teflon faced #845 stopper previously was utilized in the manufacturer of Parenteral Dilantin supplied in sterile disposable syringes.

The firm concludes that based on the approved use of the #845 stopper in other parenteral solutions, the previous use of teflon faced #845 stoppers in the manufacture of Parenteral Dilantin, the information on clear yellow discoloration in the product's labeling, and the stability profile of this lot of Dilantin, the probability of serious adverse health consequences from exposure to Parenteral Dilantin, lot 00515P, is remote.

5) VOLUME OF PRODUCT IN COMMERCE:

A total of 15,157 packages was released for distribution from the firm's Elk Grove, IL and Lititz, PA distribution centers (DC). At the time of the recall there was no product remaining in either DC. The quantity returned will be documented at the completion of the recall.

DC	QTY	REL DATE	SHIP START	SHIP END
--	---	-----	-----	-----
Elk Gr.	7800	01/31/95	02/02/95	05/25/95
Lititz	7357	02/01/95	02/02/95	06/15/95

6) DISTRIBUTION PATTERN:

The recall was directed to the dispensing level.

The lot was distributed to [redacted] direct accounts, primarily drug wholesale distributors. No foreign accounts were involved. A breakdown of consignees is as follows:

Designation	Number of Accounts
-----	-----
Free Goods Account	[redacted]
Wholesalers	[redacted]
Physician Supplier	[redacted]
Proprietary Hospital	[redacted]
Non-Profit Hospital	[redacted]
HMO with Hospital	[redacted]
Clinics/Physicians	[redacted]
Federal Government Facility	[redacted]
V.A. Facility	[redacted]
Military Facility	[redacted]
Federally Funded Facility	[redacted]
City Facility	[redacted]
Buying Group	[redacted]
Public Health Service	[redacted]
Not/Profit HMO w Dedicated Pharmacy	[redacted]
	-----
Total	[redacted]

7) FIRM'S RECALL STRATEGY:

The recall was directed to the dispensing level.

The direct accounts were notified of the recall on July 14, 1995 via certified mail, return receipt requested. In the recall letter, the firm instructed accounts to examine their inventory to determine if they had any of the referenced lot in stock. If so, they were requested to discontinue dispensing the lot and promptly return it to Parke-Davis. The firm also asked accounts that if they had further distributed to other accounts they should conduct a sub-recall for the lot.

The firm plans to send a second recall notification, or, contact where feasible, the non-respondents by phone. At the close of the recall, the recalled product will be destroyed by incineration. Destruction will be carried out after obtaining approval from the FDA.

8) FIRM OFFICIAL:

All official correspondence connected with the recall should be directed to:

Robert J. Sheroff

Vice President,  
Pharmaceutical Quality Operations, Worldwide  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-5390  
Fax: (201) 631-7722

Media inquiries should be directed to:

Mr. Peter Wolf  
Corporate Public Affairs  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-6696

9) DISTRICT AUDIT PROGRAM:

DET-DO obtained recall information from the firm's headquarters in Morris Plains, NJ. On-site inspection at the Rochester facility was not conducted at this time, however, the situation may be covered during an upcoming scheduled inspection.

DET-DO will monitor the firm's recall to completion. CDER has assigned Level E (None) FDA audit checks. No audit assignment will be issued.

Date: Mon Aug 07, 1995 3:59 pm EST  
From: DET-DO FDA / MCI ID: 611-5836

TO: CDER-COM-IO FDA / MCI ID: 621-9259  
TO: ORA-DEEO FDA / MCI ID: 626-8941  
TO: PRESS-PKLN FDA / MCI ID: 632-3149  
TO: PRESS-WASH FDA / MCI ID: 622-9289  
TO: CHI-FO FDA / MCI ID: 633-3111  
TO: \* DET-DO FDA / MCI ID: 611-5836  
Subject: PARKE-DAVIS DILANTIN RECALL RECOMMENDATION

DATE: AUGUST 4, 1995

TO: ROCKVILLE/CDER/OC/RECALL STAFF/HFD-300  
ATTN: GUST KOUSTENIS

FROM: DET-DO/JUDITH A. JANKOWSKI, R & E COORDINATOR/HFR-MW295

INFO: ROCKVILLE/ORA/DEEO/EMERG OPN BRANCH/HFC-162  
ROCKVILLE/ACPA/FDA PRESS OFFICE/HFI-20  
WASHINGTON/ACPA/FDA ENFORCEMENT REPORT STAFF/HFI-21  
CHI-FO/RFDD/HFR-MW1  
DET-DO/DIB/HFR-MW250

SUBJECT: ALERT TO RECALL SITUATION AND RECOMMENDATION FOR HEALTH  
HAZARD EVALUATION AND RECALL NUMBER

-----  
RECOMMENDATION FOR FIRM-INITIATED RECALL

PAC CODE: 56002  
PRODUCT CODE: 61MCP24  
CFN: 1818977  
DISTRICT: 9 (Detroit)  
REASON: Complaints of discolored product  
RECALL STATUS: On-going

1) PRODUCTS UNDER RECALL:

Dilantin brand Phenytoin Sodium Injection 100 mg in 2 mL,  
USP

The product is supplied as a package containing ten-2 mL  
steri-dose syringes. The lot was shipped to our Elk-Grove  
(Illinois) and Lititz (Pennsylvania) customer service  
centers for distribution.

2) CODE:

Lot No. 00515P, N 0071-4488-47, exp date, 11/96

3) RECALLING FIRM/MANUFACTURER:

Recalling Firm: The Parke-Davis Division of  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950

Manufacturer: Warner-Lambert Company  
Parke-Davis  
Sterile Products Division  
870 Parkdale Road  
Rochester, MI 48307

4) REASON FOR RECALL RECOMMENDATION:

Investigation triggered by a customer complaint about discolored product revealed that part of lot 00515P had been manufactured using incorrect stoppers. The discoloration was probably caused by the use of #845 gray stoppers instead of #1816 gray stoppers which are approved for the product. Further investigation showed that no discolored syringes were found in any stability or reserve samples for 1994 and 1995 other than lot 00515P which was recalled to the dispensing level.

The firm has not determined the exact nature and etiology of the clear yellow discoloration at this time. The firm feels the discoloration appears to be related to the process causing yellow discoloration referred to in the prescribing information for the product. The labeling for Parenteral Dilantin states, "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit...The solution is suitable for use as long as it remains free of haziness and precipitate. Upon refrigeration or freezing, a precipitate might form; this will dissolve again after the solution is allowed to stand at room temperature. The product is still suitable for use. Only a clear solution should be used. The faint yellow coloration may develop; however, this has no effect on the potency of the solution." This statement in the labeling informs the health care provider that parenteral Dilantin solution is suitable for use regardless of the presence of a faint clear yellow coloration.

The firm feels two additional considerations are relevant to their opinion. This is that stopper #845 is approved for use as part of the container system for other parenteral solutions and a teflon faced #845 stopper previously was utilized in the manufacturer of Parenteral Dilantin supplied in sterile disposable syringes.

The firm concludes that based on the approved use of the #845 stopper in other parenteral solutions, the previous use of teflon faced #845 stoppers in the manufacture of



Parenteral Dilantin, the information on clear yellow discoloration in the product's labeling, and the stability profile of this lot of Dilantin, the probability of serious adverse health consequences from exposure to Parenteral Dilantin, lot 00515P, is remote.

5) VOLUME OF PRODUCT IN COMMERCE:

A total of 15,157 packages was released for distribution from the firm's Elk Grove, IL and Lititz, PA distribution centers (DC). At the time of the recall there was no product remaining in either DC. The quantity returned will be documented at the completion of the recall.

DC	QTY	REL DATE	SHIP START	SHIP END
--	---	-----	-----	-----
Elk Gr.	7800	01/31/95	02/02/95	05/25/95
Lititz	7357	02/01/95	02/02/95	06/15/95

6) DISTRIBUTION PATTERN:

The recall was directed to the dispensing level.

The lot was distributed to ~~some~~ direct accounts, primarily drug wholesale distributors. No foreign accounts were involved. A breakdown of consignees is as follows:

Designation	Number of Accounts
-----	-----
Free Goods Account	<del>          </del>
Wholesalers	<del>          </del>
Physician Supplier	<del>          </del>
Proprietary Hospital	<del>          </del>
Non-Profit Hospital	<del>          </del>
HMO with Hospital	<del>          </del>
Clinics/Physicians	<del>          </del>
Federal Government Facility	<del>          </del>
V.A. Facility	<del>          </del>
Military Facility	<del>          </del>
Federally Funded Facility	<del>          </del>
City Facility	<del>          </del>
Buying Group	<del>          </del>
Public Health Service	<del>          </del>
Not/Profit HMO w Dedicated Pharmacy	<del>          </del>
-----	-----
Total	<del>          </del>

7) FIRM'S RECALL STRATEGY:

The recall was directed to the dispensing level.

The direct accounts were notified of the recall on July 14, 1995 via certified mail, return receipt requested. In the recall letter, the firm instructed accounts to examine their

inventory to determine if they had any of the referenced lot in stock. If so, they were requested to discontinue dispensing the lot and promptly return it to Parke-Davis. The firm also asked accounts that if they had further distributed to other accounts they should conduct a sub-recall for the lot.

The firm plans to send a second recall notification, or, contact where feasible, the non-respondents by phone. At the close of the recall, the recalled product will be destroyed by incineration. Destruction will be carried out after obtaining approval from the FDA.

8) FIRM OFFICIAL:

All official correspondence connected with the recall should be directed to:

Robert J. Sheroff  
Vice President,  
Pharmaceutical Quality Operations, Worldwide  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-5390  
Fax: (201) 631-7722

Media inquiries should be directed to:

Mr. Peter Wolf  
Corporate Public Affairs  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-6696

9) DISTRICT AUDIT PROGRAM:

DET-DO obtained recall information from Uma Iyer, Senior manager, Quality Compliance, Warner-Lambert Company, Morris Plains, NJ. On-site inspection at the Rochester facility was not conducted at this time, however, the situation may be covered during an upcoming scheduled inspection.

DET-DO will monitor the recall to completion. Recommend Level E (None) FDA audit checks based on firm recall history.

Photocopy of firm's recall packet sent to HFD-300 on 8/8/95.

10) RECOMMENDING OFFICIAL: Judith A. Jankowski, R & E  
Coordinator, DET-DO

CONCURRENCE: Brenda J. Holman, District Director, DET-DO



April 16, 1996

Ms. Sandra Williams  
Compliance Officer  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

Re: Recall of Dilantin 100 mg/2 mL Injection Lot 00515P, D-232-5 and Lot 00815P, D-005-6:  
Destruction Documentation

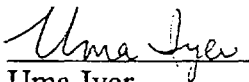
Dear Ms. Williams:

Enclosed herewith, please find the manifest and the packing slips for the destruction of Dilantin Injection lots 00515P and 00815P recalled by our firm on July 14, 1995 and August 11, 1995. The recalled material was destroyed by incineration on February 1, 1996. [REDACTED] and Mr. Victor Minicozzi of Warner-Lambert witnessed the destruction.

As you are aware from our telephone conversations that the seal on the truck containing the recalled product was found to be broken. An investigation was conducted and a report prepared to document the events starting with the packing of product for transportation to the completion of destruction. Despite the broken seal, all pallets were accounted for as borne out by the statement made by Mr. [REDACTED] of [REDACTED]. I have enclosed copies of the investigation report from [REDACTED], the product disposal report from Warner-Lambert's security office, and the signed manifest.

I am in receipt of your letter dated 1/9/96 officially closing out the recalls. Please call me at (201) 540-6528 if you have any further questions.

Sincerely,

  
Uma Iyer

Sr. Manager, Quality Compliance

copies w/o attachment:

C. Blewett  
L. Dell  
D. Krajewski  
R. Sheroff

Date: January 9, 1996  
From: Sandra Williams, Compliance Officer  
Subject: Recall Termination Recommendation, Class III  
Firm Initiated Recall No. D-232-5  
To: CDER, Office of Compliance, Recall Section, HFD-300

Recalling Firm: Parke-Davis division  
Warner-Lambert Company  
Morris Plains, NJ

Manufacturer: Warner-Lambert Company  
Parke-Davis Sterile Products Division  
870 Parkdale Rd.  
Rochester, MI. 48307

#### Section I - Recall Data

1. Recall Number: D-232-5
2. Product: Dilantin 100 mg/2 mL Injection, lot 00515P.
3. Quantity of product recovered: 24,451 syringes.
4. Disposition of returned product and held stock: As of December 1995, all stocks of this product had been removed to the firm's contract disposal company and, thus, there is no possibility of reshipment of product.
5. Samples collected: none
6. Date recall completed: December 14, 1995.

#### Section II - Verification of Effectiveness By Firm

7. Date and method of notification and number of consignees notified of the recall: Recall notifications were sent on 7/14/95 to [REDACTED] direct accounts via certified mail, return receipt requested.
8. Number of consignees responding to the recall communication: [REDACTED] of the [REDACTED] accounts responded to the recall by filling out the business reply cards. Of these, [REDACTED] customers indicated having a total of twenty four thousand one hundred and eighty (24,180) syringes on hand. There were [REDACTED] non-responders (i.e., no business reply cards) to the recall. Of these, [REDACTED] accounts returned product bringing down the number of

non-responders to the recall to [REDACTED]. Of these [REDACTED] non-responders, all but [REDACTED] accounts received the recall notification as verified by proof of delivery. The percentage of responders and non-responders to the recall are [REDACTED] and [REDACTED] respectively.

9. Number, type, and results of effectiveness checks made: Effectiveness check questionnaires were sent to seven (7) accounts via certified mail, return receipt requested. All seven responded to the questionnaire. One account responded that they had not received the recall notification. This account did receive the notification as verified by their business reply card where they had indicated having none of the lot on hand.
10. Further information pertinent to the evaluation of the effectiveness of the firm's recall: none

#### Section III - Results of FDA Audit Checks

11. Number of audit checks; how conducted: None
12. Breakdown of audit check results: n/a
13. Delays encountered in firm's recall: n/a

#### Section IV - Analysis of Recall

14. Nature of violation/problem: Complaints of discolored product. The firm had used an incorrect stopper, in that a #845 gray stopper was used instead of a #1816 gray stopper. The #845 gray stopper was approved for use on other parenteral solutions, teflon-faced #845 stoppers had been previously used by the firm, and the product's labeling discusses the possibility of discolored product and provides instructions should it be found.
15. Action firm has taken to prevent similar occurrences: The stopper supplier was audited in May 1995 and there are no outstanding issues.
16. District follow-up conducted: None.
17. District review of total effort: effective
18. Legal action: none

Recommended/Prepared by:

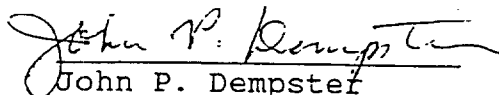
Sandra Williams  
Sandra Williams  
Compliance Officer  
Detroit District Office

1/9/96  
Date

Concur:

Disapprove:

Date: 1/9/96



John P. Dempster  
Director, Field Operations Branch  
Detroit District Office

Orig:HFD-300

cc:HFC-162

HFA-224

Recall file ( D-232-5)

EF

Kal R/P

GR R/P

**PARKE-DAVIS**  
People Who Care

January 18, 1996

Ms. Sandra Williams  
Compliance Officer  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

**Re: Status of Recalled Products**

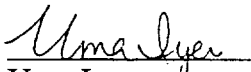
Dear Ms. Williams,

Per your request, I am updating you on the destruction status of some of our products that have been recalled. We are currently awaiting destruction of Dilantin injection lots 00515P (D-232-5) and 00815P (D-005-6), and Surital multiple lots (D-215/217-5). Surital is a controlled substance and, at this time, we are waiting to obtain DEA approval for destruction. It is hoped that a date can be fixed for the first week in February. Both lots of Dilantin injection are expected to be destroyed as hazardous substance towards the end of this month.

I wish to assure you that any product remaining at the distribution centers (DC) was quarantined at the DC at the time of the recall, and has now been shipped to Franklin, NJ where all recalled products are returned by our customers. I shall send you the destruction documentation for each of the recalls as soon as the process is completed.

I trust this answers your concern about the delay in the destruction of the recalled lots. Please call me at (201) 540-6528 if you have any additional questions.

Sincerely,

  
Uma Iyer

Sr. Manager  
Quality Compliance

copies:

C. Blewett L. Calitri L. Dell D. Krajewski R. Sheroff

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260  
FAX: 313-226-3076

January 9, 1996

Ms. Uma Iyer, Senior Manager  
Quality Compliance  
Parke-Davis Division  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950

RE: Recall # D-232-5  
D-005-6

Dear Ms. Iyer:

The Food and Drug Administration has completed the audits of your firm's actions concerning:


Recall Number D-232-5; Dilantin 100 mg/2 mL Injection, lot 00515P  
Recall Number D-005-6; Dilantin 100 mg/2 mL Injection, lot 00815P

The products were recalled because of discoloration.

We conclude that the recalls have been completed and there has been proper disposition of the recalled products. Therefore, FDA considers the recalls terminated.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure compliance with the Food, Drug and Cosmetic Act in the future.

Sincerely yours,

  
Brenda J. Holman  
District Director  
Detroit District

cc: Recall File # D-232-5  
D-005-6

EF

BJH:SW:bjm



**PARKE-DAVIS**  
People Who Care

December 14, 1995

Ms. Judith A. Jankowski  
Recall and Emergency Coordinator  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

**Re: Recall of Dilantin 100 mg/2 mL Injection, D-232-5**

Dear Ms. Jankowski,

The Parke-Davis division of Warner-Lambert Company initiated a recall for lot 00515P of Dilantin Injection on July 14, 1995. The information presented below is in response to your letter dated August 17, 1995 on the recall.

**1. Number of consignees notified of the recall, and date and method of notification.**

Recall notifications, dated 7/14/95, were sent on 7/14/95 to [REDACTED] direct accounts via certified mail, return receipt requested.

**2. Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.**

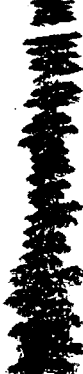
[REDACTED] of the [REDACTED] accounts responded to the recall by filling out the business reply cards. Of these, [REDACTED] customers indicated having a total of twenty four thousand one hundred and eighty (24,180) syringes on hand.

**3. Number of consignees that did not respond.**

There were [REDACTED] non-responders (i.e., no business reply cards) to the recall. Of these, [REDACTED] accounts returned product bringing down the number of non-responders to the recall to [REDACTED]. Of these [REDACTED] non-responders, all but [REDACTED] accounts received the recall notification as verified by proof of delivery. The percentage of responders and non-responders to the recall are [REDACTED] and [REDACTED], respectively. The number of non-responders is sorted by trade class in Table I below:

Ms. Judith A. Jankowski  
December 14, 1995  
Dilantin 100 mg/2 mL Injection

Table I - Non-responders grouped by Trade Class

Trade Class	Designation	Number of non-responders
02	Free Goods Account	
40	Wholesalers	
52	Non-Profit Hospital	
53	HMO with Hospital	
71	Federal Government Facility	
73	Military Facility	
74	Federally Funded Facility	
75	City Facility	
79	Public Health Service	
95	Not for Profit HMO with Dedicated Pharmacy	

4. Number of products returned or corrected by each consignee contacted and the quantity of product accounted for.

Product returns are listed in Table II below.

Table II - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

CCI

Ms. Judith A. Jankowski  
December 14, 1995  
Dilantin 100 mg/2 mL Injection

Table II contd. - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

*CC I*

Ms. Judith A. Jankowski  
December 14, 1995  
Dilantin 100 mg/2 mL Injection

Table II contd. - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

CCI

Ms. Judith A. Jankowski  
December 14, 1995  
Dilantin 100 mg/2 mL Injection

Table II contd. - Product Returned

Account #	Customer Name	Quantity*
-----------	---------------	-----------

CCI

Total Quantity\* ..... 24451

\* Quantity refers to number of syringes

5. Number and results of effectiveness checks that were made and method in which conducted.

Per your letter of 8/17/95, a level D effectiveness check was conducted. Effectiveness check questionnaires were sent to seven (7) accounts via certified mail, return receipt requested. All seven responded to the questionnaire. One account, [REDACTED], responded that they had not received the recall notification. This account did receive the notification as verified by their business reply card where they had indicated having none of the lot on hand.

6. Estimated time frame for completion of recall.

It is our determination that we have taken the recall for Dilantin Injection to completion. At this time we request your permission to destroy the material and close out the recall.

7. Corrective action taken to prevent similar problems in future.

The stopper supplier was audited in May 1995 and there are no outstanding issues.

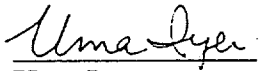
Ms. Judith A. Jankowski  
December 14, 1995  
Dilantin 100 mg/2 mL Injection

**Summary:**

Recall for Dilantin Injection lot 00515P was initiated to the secondary level on July 14, 1995. The response rate to the recall was ██████%. Level D effectiveness check was completed. Permission to destroy the recalled material is requested.

I trust this completes the information on the recall of Dilantin Injection. Please call me at (201) 540-6528 if you have any questions in this matter.

Sincerely,

  
Uma Iyer

Sr. Manager  
Quality Compliance

copies:

C. Blewett  
L. Calitri  
L. Dell  
D. Krajewski  
R. Sheroff



CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260  
FAX: 313-226-3076

August 17, 1995

Mr. Robert J. Sheroff, Vice President  
Pharmaceutical Quality Operations, Worldwide  
Warner-Lambert Company  
182 Tabor Road  
Morris Plains, New Jersey 07950

RE: Recall No. D-213-5  
Recall No. D-214-5  
Recall No. D-215/217-5  
Recall No. D-232-5

Dear Mr. Sheroff:

We agree with your firm's decision to recall the following Parke-Davis products manufactured at your Rochester, Michigan facility: Chloromycetin Hydrocortisone Ophthalmic (Chloramphenicol and Hydrocortisone Acetate for Ophthalmic Suspension) (Recall No. D-213-5); 10 g. Elase-Chloromycetin Ointment (Fibrinolysin and Deoxyribonuclease Combined (Bovine) with Chloramphenicol Ointment) (Recall No. D-214-5); Surital (Thiamylal Sodium for Injection, USP) 1 g., 5 g., and 10 g. (Recall No. D-215/217-5); and Dilantin brand Phenytoin Sodium Injection 100 mg. (Recall No. D-232-5).

We have reviewed your actions and conclude that they meet the formal definition of a "Recall". This is significant, as your actions are an alternative to a Food and Drug Administration legal action to remove your defective product from the market. These recalls will be reported in an upcoming issue of the FDA Weekly Enforcement Report.

It is suggested that you follow the FDA's "Enforcement Policy-Recalls (including Product Corrections) - Guidelines on Policy, Procedures and Industry Responsibilities" issued June 16, 1978 in conducting your recall. Enclosed you will find a copy of this "Enforcement Policy" as well as a copy of the FDA's "Methods for Conducting Recall Effectiveness Checks".

Recall No. D-213-5 has been classified by the FDA as a Class III recall, since FDA considers the drug product to be adulterated in that the associated water diluent does not meet stability specifications. Our evaluation indicates that this recall should be conducted to the direct account level and that level E (none) effectiveness checks should be conducted by your firm. No further effectiveness check activities are required at this time.

Recall No. D-214-5 has been classified by the FDA as a Class III recall. The product is considered to be adulterated in that it does not meet stability specifications. Our evaluation indicates that this recall should be conducted to the secondary account level and that level D effectiveness checks should be conducted by your firm. Level D effectiveness checks means that your firm should make follow-up contacts at 2% of your consignees, and confirm that they were notified and followed your firm's recall instructions.

Recall No. D-215/217-5 has been classified by the FDA as a Class III recall. The product is considered to be adulterated in that it does not meet stability specifications for potency. Our evaluation indicates that this recall should be conducted to the secondary account level and that level D effectiveness checks should be conducted by your firm.

Recall No. D-232-5 has been classified by the FDA as a Class III recall. The product is considered to be adulterated in that it may be discolored as a result of using an incorrect stopper. Our evaluation indicates that this recall should be conducted to the secondary account level and that level D effectiveness checks should be conducted by your firm.

In addition to your recall efforts, it is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped.

Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse. We therefore urge you to immediately begin making plans to destroy the product or



recondition it to bring it into compliance with the law. Either method should be done under the supervision of an investigator from this office. Our Detroit District office should be notified prior to the initiation of reconditioning or destruction of the recalled products.

We request that you advise us within ten days of the steps you have taken to insure that the recalled merchandise is properly inventoried and maintained to prevent unintended use or shipment, and provide your method of disposition of the returned goods.

In addition, we request that you submit to our Detroit District office a recall status report for each recall at monthly intervals until your recalls are completed. These recall status reports should contain the following information:

- (1) Number of consignees notified of the recall, and date and method of notification.
- (2) Number of consignees responding to the recall communication and quantity of products on hand at the time it was received.
- (3) Number of consignees that did not respond.
- (4) Quantity of each of the products on hand at your firm when recall initiated.
- (5) Quantity of each of the products returned or corrected by consignees and the quantity of products accounted for.
- (6) Number, method of conducting, and results of effectiveness checks that were made.
- (7) Estimated time frames for completion of the recall.
- (8) What corrective action have you taken to prevent occurrence of similar design problems in the future?

These status reports and your response to this letter should be addressed to: Food and Drug Administration, 1560 East Jefferson, Detroit, Michigan 48207, Attention: Judith A. Jankowski, Recall Coordinator.

Page 4 Mr. Sheroff, Warner-Lambert Co., Morris Plains, N.J.  
Recall # D-213-5, D-214-5, D-215/217-5, D-232-5

Our judgment regarding the effectiveness of your recall will largely be based upon your implementation of the enclosed recall guidelines. Please be advised that failure to conduct an effective recall could result in seizure of the violative product in commerce or other legal sanctions under the Food, Drug and Cosmetic Act.

Your cooperation in this matter is important for the protection of the general public.

Sincerely yours,



Brenda J. Holman  
District Director  
Detroit District

Enclosures:

Copy of Federal Register, Vol. 43, No. 117, pages 26218-26221

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Copy of FDA's "Methods for Conducting Recall Effectiveness Checks"

cc: Uma Iyer, Senior Manager, Quality Compliance  
Warner-Lambert Company, Morris Plains, NJ



## URGENT: DRUG RECALL

INCORRECT STOPPER  
August 11, 1995

Re: Dilantin® (Phenytoin Sodium Injection, USP) 100 mg in 2 mL,  
Lot 00815P N 0071-4488-47 (Ten 2-mL steri-dose® syringes)

Dear Customer:

The Parke-Davis division of Warner-Lambert Company is voluntarily recalling Dilantin® (Phenytoin Sodium Injection, USP) 100 mg in 2 mL steri-dose® syringe lot 00815P. The recall was initiated when it was determined that lot 00815P includes a small number of syringes incorporating three-rib stoppers not approved for use in this product. The three-rib stoppers are approved for use in other parenteral solutions and the probability of serious adverse health consequences from exposure to this lot is remote.

The recall of lot 00815P is being extended to the **dispensing** level.

Our records indicate that you may have received shipment of lot 00815P manufactured by Parke-Davis and distributed between February and July, 1995. If you have any of lot 00815P on hand, please stop dispensing and promptly return it to:

PARKE-DAVIS  
MUNSONHURST ROAD COMPLEX  
FRANKLIN, NJ 07416

If you have further distributed lot 00815P to other accounts please communicate this recall information to these accounts immediately. Your accounts should return the product directly to the above address and do not need to fill out the business reply card. Further authorization is not required to return the product. Reimbursement for the returned goods and shipping cost will be made by credit memorandum or check.

**IT IS VERY IMPORTANT THAT YOU FILL IN THE REQUESTED INFORMATION IN THE ENCLOSED RESPONSE CARD AND RETURN IT WITHIN FIVE (5) DAYS EVEN IF YOU HAVE NONE OF THE REFERENCED LOT ON HAND. YOU MAY ALSO FAX YOUR RESPONSE TO (201) 209-0794.**

This recall is being conducted with the knowledge of the Food and Drug Administration. Your immediate attention and cooperation are appreciated. We sincerely regret any inconvenience you have been caused by this action. If you have any questions, please contact our Medical Affairs Department at 1-800-223-0432.

Sincerely,

Leonard Dell  
Vice President  
Pharmaceutical Quality Assurance

**PLEASE FILL OUT AND RETURN IMMEDIATELY**

Dilantin® (Phenytoin Sodium Injection, USP)  
100 mg in 2 mL  
in 2-mL steri-dose® syringes  
0071-4488-47

Lot No.	No. of Packages to be Returned	None in Stock
0071-4488-47	00815P	

PRINTED NAME \_\_\_\_\_

TITLE \_\_\_\_\_ PHONE NO. \_\_\_\_\_

SIGNATURE \_\_\_\_\_

If you distribute, did you notify your consignees? YES  NO

How were such notifications carried out? Our Letter  Your Letter  Phone

Date of Notification: \_\_\_\_\_

OTHER: \_\_\_\_\_

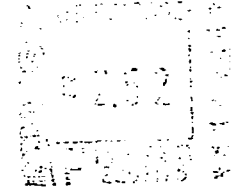
Judith Jankowski, Recall Coordinator  
Food & Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

201 Tabor Road  
Morris Plains, N.J.  
07950

**CERTIFIED**

Z 178 080 001

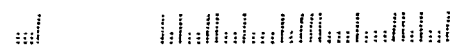
**MAIL**



**PARKE-DAVIS**  
Care

Judith Jankowski, Rcl. Coordinator  
Food and Drug Administration  
Detroit Districe Office  
1560 Jefferson Avenue  
Detroit, MI 48207

**DRUG RECALL**



From: Ms. Judith Jankowski  
Recall Coordinator  
Food & Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

TO: PARKE-DAVIS  
MUNSONHURST RD. COMPLEX  
FRANKLIN, NJ 07416

July 20, 1995

Ms. Judith A. Jankowski  
Recall and Emergency Coordinator  
Food and Drug Administration  
Detroit District Office  
1560 Jefferson Avenue  
Detroit, MI 48207

**Re: Recall of Dilantin® Injection**

Dear Ms. Jankowski,

Enclosed please find the follow-up information pertaining to the recall of Dilantin® Injection initiated by our firm on July 14, 1995. I have answered the questions in the same order as they appear in the recall questionnaire.

**1. Product:**

---

Dilantin® 100 mg in 2 mL  
Phenytoin Sodium Injection, USP

**2. Code:**

Lot 00515P, N 0071-4488-47, expiration date, 11/96. The product is supplied as a package containing ten-2 mL steri-dose® syringes. The lot was shipped to our Elk-Grove (Illinois) and Lititz (Pennsylvania) customer service centers for distribution.

**3. Recalling Firm/Manufacturer:**

The recall was initiated by:

The Parke-Davis Division of Warner-Lambert Co.  
182 Tabor Road  
Morris Plains, NJ 07950

Judith A. Jankowski  
FDA, Detroit District Office  
Dilantin<sup>®</sup> Injection Recall Questionnaire - July 20, 1995

The recalled product was manufactured at the Warner-Lambert Co. facility located at the following address:

Warner-Lambert Company  
Parke-Davis  
Sterile Products Division  
870 Parkdale Road  
Rochester, MI 48307

**4. Reason for Recall:**

Investigation triggered by a customer complaint about discolored product revealed that part of lot 00515P had been manufactured using incorrect stoppers. The discoloration was probably caused by the use of 845 gray stoppers instead of 1816 gray stoppers which are approved for the product. Further investigation showed that no discolored syringes were found in any stability or reserve samples for 1994 and 1995 other than lot 00515P which was recalled to the dispensing level.

~~Health Hazard Evaluation:~~

See Attachment I.

**5. Volume of Product in Commerce:**

A total of 15,157 packages was released for distribution. The table below gives the quantity of product at, and dates of transaction from the Elk Grove and Lititz distribution centers (DC). At the time of the recall there was no product remaining in either DC. The quantity returned will be documented at the completion of the recall.

DC	Quantity	Receival Date	Shipping Start Date	Shipping End Date
Elk Grove	7800	01/31/95	02/02/95	05/25/95
Lititz	7357	02/01/95	02/02/95	06/15/95

Judith A. Jankowski  
FDA. Detroit District Office  
Dilantin® Injection Recall Questionnaire - July 20, 1995

**6. Distribution Pattern:**

The recall was directed to the dispensing level. The information pertaining to the distribution pattern is provided in Attachment II.

Attachment II-a gives the list of accounts in zip code sequence and the list of government accounts is provided in Attachment II-b. A summary report for the distribution pattern is found in Attachment II-c. A total of nine identical duplicate accounts (*see* Attachment II-d) was deleted from the zip code sequence list. Attachment II-e contains numerical code designations for trade classes and the number of accounts in each trade class after elimination of the nine identical duplicates shown in Attachment II-d. No foreign accounts were involved.

**7. Firm's Recall Strategy:**

The direct accounts were notified of the recall on July 14, 1995 via certified mail, return receipt requested. In the recall letter, we instructed our accounts to examine their inventory to determine if they had any of the referenced lot in stock. If so, we requested that they discontinue dispensing the lot and promptly return it to Parke-Davis. We also asked our ~~accounts that if they had further distributed to other accounts they should conduct a sub-recall for the lot.~~

In the past, we have improved the response rate to our recalls by sending a second recall notification, or, by contacting where feasible, the non-respondents by phone. At the close of the recall, the recalled product will be destroyed by incineration. Destruction will be carried out after obtaining approval from the FDA.

**8. Firm's Official:**

All official correspondence connected with the recall should be directed to:

Robert J. Sheroff  
Vice President,  
Pharmaceutical Quality Operations, Worldwide  
Warner-Lambert Co.  
182 Tabor Road  
Morris Plains, NJ 07950

Phone: (201) 540-5390  
Fax: (201) 631-7722

Judith A. Jankowski  
FDA, Detroit District Office  
Dilantin® Injection Recall Questionnaire - July 20, 1995

Media inquiries should be directed to:

Mr. Peter Wolf  
Corporate Public Affairs  
Warner-Lambert Company  
201 Tabor Road  
Morris Plains, NJ 07950  
Phone: (201) 540-6696

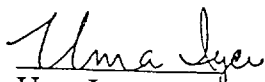
**Additional Product Information:**

Three sets of syringe labels, inserts, and cartons are included in Attachment III.

Three samples of the recall package including the letter, business reply card, and shipping label for product return are included in Attachment IV.

This concludes the response to the recall questionnaire. In addition to the hard copy, I have sent you this report, electronically, without the attachments found in I, II-a, II-b, II-c, II-d, III, and ~~IV~~ to the address: JJANKOWSKI@FDAEM.SSW.DHHS.GOV@PMDF@IN. If you have any questions with respect to this recall, you can reach me either by phone at (201) 540-6528 or by fax at (201) 631-7722.

Sincerely,

  
Uma Iyer  
Senior Manager  
Quality Compliance

copies:

C. Blewett  
C. Curtin  
L. Dell  
D. Krajewski  
R. Sheroff



**PARKE-DAVIS** MEDICAL AFFAIRS  
People Who Care

**Memorandum**

To: Of Record

Date: 7/10/95

From: Bruce A. Boselli, M.D. *BAB*

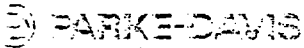
Subject: Medical Opinion - Parenteral Dilantin (Phenytoin Sodium Injection, USP) Lot# 00515P

Six month stability testing of Parenteral Dilantin (Phenytoin Sodium Injection, USP) lot# 00515P supplied in sterile disposable syringes revealed certain syringes were manufactured with stopper 845 rather than stopper 1816. Dilantin (Phenytoin Sodium Injection, USP) contained in syringes manufactured with stopper 845 meet all stability specifications for parenteral phenytoin and these syringes appear to be associated with a clear yellow discoloration of the parenteral phenytoin solution.

The exact nature and etiology of the clear yellow discoloration have not been established at this time. The discoloration appears to be related to the process causing yellow discoloration referred to in the prescribing information for the product. The labeling for Parenteral Dilantin (Phenytoin Sodium Injection, USP) states "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. . . . The solution is suitable for use as long as it remains free of haziness and precipitate. Upon refrigeration or freezing, a precipitate might form; this will dissolve again after the solution is allowed to stand at room temperature. The product is still suitable for use. Only a clear solution should be used. A faint yellow coloration may develop; however, this has no effect on the potency of the solution." This statement in the labeling informs the health care provider that parenteral Dilantin solution is suitable for use regardless of the presence of a faint clear yellow coloration.

Two additional considerations relevant to this opinion are stopper 845 is approved for use as part of the container system for other parenteral solutions and a teflon faced 845 stopper previously was utilized in the manufacture of Parenteral Dilantin (Phenytoin Sodium Injection, USP) supplied in sterile disposable syringes.

Therefore, based on the approved use of the 845 stopper in other parenteral solutions, the previous use of teflon faced 845 stoppers in the manufacture of Parenteral Dilantin (Phenytoin Sodium Injection, USP), the information on clear yellow discoloration in the product's labeling, and the stability profile of this lot of Dilantin the probability of serious adverse health consequences from exposure to Parenteral Dilantin (Phenytoin Sodium Injection, USP) lot 00515P is remote.



INCORRECT STOPPER  
July 14, 1995

Re: Dilantin® (Phenytoin Sodium Injection, USP) 100 mg in 2 mL,  
Lot 00515P N 0071-4488-47 (Ten 2-mL steri-dose® syringes)

Dear Customer:

The Parke-Davis division of Warner-Lambert Company is voluntarily recalling Dilantin® (Phenytoin Sodium Injection, USP) 100 mg in 2 mL steri-dose® syringe lot 00515P. The recall was initiated when it was determined that the referenced lot includes a small number of syringes incorporating three-rib stoppers not approved for use in this product. The three-rib stoppers are approved for use in other parenteral solutions and the probability of serious adverse health consequences from exposure to this lot is remote.

The recall of lot 00515P is being extended to the dispensing level.

Our records indicate that you may have received shipment of this lot manufactured by Parke-Davis. Lot 00515P was distributed between February and June, 1995. If you have any of this lot on hand, please stop dispensing and promptly return it to:

PARKE-DAVIS  
MUNSONHURST ROAD COMPLEX  
FRANKLIN, NJ 07416

If you have further distributed this lot to other accounts please communicate this recall information to these accounts immediately. Your accounts should return the product directly to the above address and do not need to fill out the business reply card. Further authorization is not required to return the product. Reimbursement for the returned goods and shipping cost will be made by credit memorandum or check.

**IT IS VERY IMPORTANT THAT YOU FILL IN THE REQUESTED INFORMATION IN THE ENCLOSED RESPONSE CARD AND RETURN IT WITHIN FIVE (5) DAYS EVEN IF YOU HAVE NONE OF THE REFERENCED LOT ON HAND. YOU MAY ALSO FAX YOUR RESPONSE TO (201) 209-0794.**

This recall is being conducted with the knowledge of the Food and Drug Administration. Your immediate attention and cooperation are appreciated. We sincerely regret any inconvenience you have been caused by this action. If you have any questions, please contact our Medical Affairs Department at 1-800-223-0432.

Sincerely,

Leonard Dell  
Vice President  
Pharmaceutical Quality Assurance

201 Tabor Road  
Morris Plains, NJ  
07950

 **PARKE-DAVIS**  
People Who Care

A Warner-Lambert Company

**URGENT: DRUG RECALL**

**BUSINESS REPLY MAIL**

FIRST CLASS MAIL PERMIT NO. 3 FRANKLIN, NJ

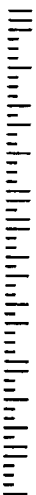
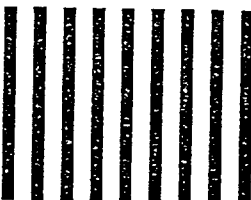
POSTAGE WILL BE PAID BY ADDRESSEE

**Parke-Davis**

P.O. Box 316  
FRANKLIN NJ 07416-9968



NO POSTAGE  
NECESSARY  
IF MAILED  
IN THE  
UNITED STATES



**PLEASE FILL OUT AND RETURN IMMEDIATELY**

Dilantin® (Phenytoin Sodium Injection, USP)  
100 mg in 2 ml  
Ten 2-ml steri-dose® syringes  
N 0071-4488-47

Lot No. \_\_\_\_\_  
N 0071-4488-47      00515P

No. of Packages  
to be Returned \_\_\_\_\_

None in  
Stock \_\_\_\_\_

PRINTED NAME \_\_\_\_\_

TITLE \_\_\_\_\_

PHONE NO. \_\_\_\_\_

SIGNATURE \_\_\_\_\_

If you distributor, did you notify your consignees? YES  NO

How were such notifications carried out? Our Letter  Your Letter  Phone

Date of Notification: \_\_\_\_\_

OTHER: \_\_\_\_\_

FROM: \_\_\_\_\_

TO: PARKE DAVIS  
MUNSONHURST RD. COMPLEX  
FRANKLIN, NJ 07416

RECALL PRODUCT ENCLOSED