

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-923

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-160	2. NDA Number(s) 20-923 (000)
3. Name and Address of Applicant (City & State): Mallinckrodt Medical, Inc. 675 McDonnell Blvd. St. Louis, MO 63042		4. AF No.	5. Supplement(s) Number(s) Date(s)
6. Drug Name: Optiray Pharmacy Bulk Package	7. Nonproprietary Name: Loversol Injection	8. Amendments & Other (reports, etc.) - Dates BC 27 Mar 98	
9. Amendment Provides For: Additional information as requested by agency via telefax on 19 Mar 98 as well as Mallinckrodt's response to FDA's comment			
10. Pharmacological Category: Contrast agent for diagnostic imaging	11. How Dispensed: <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. Related IND(s)/ NDA(s)/DMF(s)	
13. Dosage Form(s): Injection	14. Potency(ies): 350, 320, 240		
15. Chemical Name and Structure: N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl)-glycolamido]-2,4,6- triiodoisophthalamid		16. Records/Reports Current: <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed: <input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>Chemical Structure:</p> <p>Molecular Formula: C₁₈H₂₄I₃N₃O₉ Molecular Weight: 807.13</p>			
17. Comments: All of the questions pertaining to the labeling and stability study of Optiray Pharmacy Bulk Package have been addressed satisfactorily by Mallinckrodt			
18. Conclusions and Recommendations: A letter of approval to the sponsor is recommended.			
CC: Original NDA# 20-923 HFD-160/Division File HFD-160/Yongde Lu HFD-160/CSO R/D initialed by : Leutzinger			
19. REVIEWER			
Name Yongde Lu, Ph.D	Signature <i>[Signature]</i>	Date Completed 23 Apr 98	

[Handwritten initials and date]
4/24/98

MAR 10 1998

NDA 20-923

DNDC-II CHEMIST'S NDA REVIEW

DIVISION OF MEDICAL IMAGING & RADIOPHARMACEUTICAL DRUG PRODUCTS
(HFD-160)

Review of Chemistry, Manufacture, and Control

NDA # 20-923

CHEM. REVIEW # 1

REVIEW DATE

13 Feb 98

SUBMISSION TYPE
Original

DOCUMENT DATE
30 Sep 97

CEDER DATE
01 Oct 97

ASSIGNED DATE
03 Oct 97

NAME & ADDRESS OF APPLICANT:

Mallinckrodt Medical, Inc.
675 McDonnell Blvd.
St. Louis, MO 63134
Contact name: Clarice Kassoff
Sr. Regulatory Affairs Associate
Telephone #: (314)654-2000
Fax #: (314)654-3344

DRUG PRODUCT NAME

Proprietary:

Nonproprietary/USAN: _____

Code Name/#:

Chem. Type/Ther. Class:

Optiray Pharmacy Bulk Package

~~I~~oversol Injection

not specified

5 C

PHARMACOL. CATEGORY/INDICATION:

Contrast agent for diagnostic imaging

DOSAGE FORM:

Injection

STRENGTHS:

350, 320, 240 mg organically bound iodine/mL

ROUTE OF ADMINISTRATION:

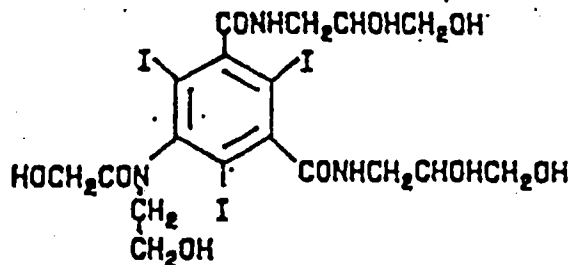
Intravascular

DISPENSED:

X Rx OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl)-glycolamido]-2,4,6-triiodoisophthalamid

Chemical Structure:



Molecular Formula: C₁₈H₂₄I₃N₃O₉

Molecular Weight: 807.13

SUPPORTING DOCUMENTS:

NDA 19-710, Ioversol, (Mallinckrodt)

RELATED DOCUMENTS:

NDA 20-327, Isovue (iopamidol) Pharmacy Bulk Package,
(Squibb Diagnostics)

DNDC-II CHEMIST'S NDA REVIEW

NDA 20-923

REMARKS/COMMENTS:

The NDA provides for a Pharmacy Bulk Package for the single use drug product Optiray (loversol Injection). The latter was currently approved under NDA 19-710. The manufacturing, packaging, testing and manufacturing site of these 200mL/250mL container are identical to that in currently approved NDA19-710, with the exception of the labeling modification necessary for a Pharmacy Bulk Package. Since NDA 190710 does not currently provide for a 200 mL fill in 250 mL bottle for Optiray 160 or Optiray 300, therefore, provision for Pharmacy Bulk Package of these two coconcentration is not included in this NDA. The draft labeling has been revised to meet the requirement of FDA Pharmacy Bulk Package Labeling Guideline. However, the copy of Carton Label was not submitted in this NDA and notation "expiration Date and Lot Number at print time" was missing on the bottle Label. A request for addition information is attached.

CONCLUSIONS & RECOMMENDATIONS:

The application is approvable pending a satisfactory response to the additional information requested.

cc:

Orig. NDA 20-923
HFD-160/Division File
HFD-820/Yongde Lu/2/23/98
HFD-160/Kathleen Hockensmith
HFD-160/Vivian Greenman
HFD-820/Gibbs
R/D init. By

/s/ 2/13/98
Yongde Lu, Ph.D., Review Chemist

/s/ 3/10/98
Eldon E. Leuzinger, Pd.D., Team Leader

Redacted

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commercial

information