CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75830

CORRESPONDENCE

ANDA 75-830

NOV - 9 2001

Faulding Pharmaceutical Company
Attention: Jatin Shah
One New England Avenue
Piscataway, NJ 08854

Dear Madam:

This is in reference to your abbreviated new drug application dated March 31, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Milrinone Lactate Injection, 1mg(base)/mL packaged in 10 mL, 20 mL, and 50 mL vials.

Reference is also made to your amendment dated September 26, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application is currently subject to a period of patent protection. Your application contains a Paragraph III Certification to each patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of this patent. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the period has expired, i.e., May 26, 2002.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60 days (but

has effectively been extended by an additional 6 months of marketing exclusivity under Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). The Modernization Act created section 505(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505(A) permits certain applications to obtain an additional six months of marketing exclusivity (pediatric exclusivity) if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population. Sanofi has submitted such information to the agency. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '951 patent has expired, i.e., currently May 26, 2002.

In order to reactivate your application prior to final approval, please submit an amendment between 60 to 90 days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional amendment containing the information described above.

Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

Please note that this drug product may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to May 26, 2002, you should amend your application accordingly.

For further information on the status of this application or prior to submitting the minor amendment, please contact Stanley Shepperson, Pharm.D., Project Manager, at 301-827-5849.

Sincerely yours,

/S/

Gary Buehler 11/9/01
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-830

Faulding Pharmaceutical Inc.
Attention: Heike Masser, Ph.D.
11 Commerce Drive
Cranford, NJ 07016

APR 19 2000

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Milrinone Lactate Injection, 1 mg/mL
10 mL and 20 mL vials

DATE OF APPLICATION: March 31, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: April 3, 2000

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Tim Ames
Project Manager
(301) 827-5849

Sincerely yours,

/S/

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ORIGINAL

Faulding Pharmaceutical Company
A division of Mayne Nickless

Mack-Cali Centre II
650 From Road
2nd Floor
Paramus
New Jersey 07652
United States

Telephone
+1 201 225 5500
Facsimile
+1 201 225 5510

www.faulding.com

VIA UPS OVERNIGHT COURIER

MINOR AMENDMENT – FINAL APPROVAL REQUESTED

March 6, 2002

ORIG AMENDMENT
N/AM

Mr. Gary Buehler, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: ANDA 75-830 – Milrinone Lactate Injection, 1 mg (base)/mL
10 mL, 20 mL and 50 mL Vials

Dear Mr. Buehler:

Reference is made to the letter of November 6th 2001 which gave tentative approval to the above referenced ANDA. The letter stated that final approval of our application may not be made effective pursuant to 21 USC 355 (j) (5) (B) (ii) of the Act until the '951 patent has expired, currently May 26, 2002. As requested in the letter, we are submitting an amendment between 60 – 90 days prior to May 26, 2002 to reactivate our application for final approval. No changes in final-printed labeling, chemistry, manufacturing, and controls have occurred since tentative approval was given.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

Jatin J. Shah

Jatin Shah, Ph.D.
Vice President, Scientific Affairs
Tel.: (201) 225 5546
Fax: (201) 225-5567

RECEIVED
MAR 1 1 2002
OGD / CDER

3/13/02

ORIGINAL

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

Faulding
World of Health

One New England Avenue
Piscataway
New Jersey 08854
United States
Telephone
+1 732 465 3600
Facsimile
+1 732 465 3630
www.faulding.com

VIA UPS OVERNIGHT COURIER

January 30, 2002

Mr. Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-27733

GENERAL CORRESPONDENCE

Re: Change of Corporate Headquarter Address

NEW CORRESP
NC

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is changing its corporate headquarters location effecting the correspondence address for the Regulatory Affairs group. Effective February 1, 2002, the Regulatory Affairs group will be located at Faulding Pharmaceutical Co., Mack Cali Centre II, 650 From Road, Second Floor, Paramus, New Jersey 07652.

Provided is a listing of Faulding ANDAs, pending applications, and supplements effected by this correspondence address change. There are no changes to any manufacturing site addresses covered in these applications. This is only a correspondence address change.

Should you have any questions, please do not hesitate to contact me. Please note our new telephone and fax number.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs
Tel: (201) 225-5546
Fax: (201) 225-5530

JS/sh

Enc.

ORIGINAL

Faulding Pharmaceuticals
A division of F H Faulding & Co Limited

Faulding
A World of Health

One New England Avenue
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United States
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+1 732 465 3600
Facsimile
+1 732 465 3630
www.faulding.com

Facsimile Transmission
301-594-0498

December 6, 2001

NEW CORRESP
NC

NAI
13-DEC-2001

Greg Davis, Branch Chief
Regulatory Support Branch
Division of Labeling and Program Support
Office of Generic Drugs
Food and Drug Administration
7520 Standish Place, HFD-610
Rockville, MD 20855

Dear Mr. Davis

This is to advise you that we have appointed Leon Lachman, Ph.D. of Lachman Consultant Services, Inc. (LCS), as regulatory consultant for Faulding Pharmaceutical Co. on FDA-related matters, effective September 5, 2001.

As a matter of record, Dr. Lachman is President of:

Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590
516-222-6222

As regulatory consultant for Faulding Pharmaceutical Co., Dr. Lachman and his associates are hereby authorized to represent Faulding Pharmaceutical Co. on official FDA consultations and related business.

Thank you, in advance, for your incorporation of this notice into the file for Faulding Pharmaceutical Co. and Butorphanol Tartrate Injection, USP, ANDA 75-170.

Sincerely,

Jatin J. Shah

Jatin J. Shah, Ph.D.
Vice President, Scientific Affairs

/JS

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VIA UPS OVERNIGHT COURIER

Amendment to Minor Amendment of September 26, 20

Faulding
A World of Health

October 26, 2001

Mr. Gary Buehler, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

N/AA

RE: ANDA 75-830 – Milrinone Lactate Injection, 1 mg (base)/mL
10 mL, 20 mL and 50 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. had submitted a minor amendment (Chemistry) on September 26, 2001 in response to your deficiency letter dated May 21, 2001.

Faulding Pharmaceutical Co. would like to amend their September 26, 2001 response to include new revised batch records for the proposed commercial batches of Milrinone Lactate Injection, 1 mg (base)/mL.

In Faulding's ANDA and subsequent amendment submissions, one of the process parameters (RPMs) was incorrectly adapted due to misreading of the RPM designation on the manufacturing tank used during production of the exhibit batch. This occurred because the procedure used was not appropriate for accurately reading the speed at which the mixer was actually rotating.

As a corrective action to avoid the type of issue that occurred with this product, the commercial batch records are revised to make them tank specific. The revised batch records are provided in **Attachment 1**. The list of differences between the previously submitted batch records and current batch records is also provided in **Attachment 1** for ease of review.

We are looking forward to your review of this Amendment and approval of this product. Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

K Patel

for Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (732) 465-3888
Fax: (732) 465-3885

CENTER FOR DRUG
OCT 2 9 2001
EVALUATION AND RESEARCH

Labeling review drafted 10/11/01 AVezza

VIA UPS OVERNIGHT COURIER

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Faulding
A World of Health

MINOR AMENDMENT

September 26, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH
SEP 2 8 2001
OGD

Mr. Gary Buehler, Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/Am

RE: ANDA 75-830 – Milrinone Lactate Injection, 1 mg (base)/mL
10 mL, 20 mL and 50 mL Vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is responding to your deficiency letter dated May 21, 2001 in which you requested additional Chemistry information at the request of the Method Validation Laboratory in Philadelphia. In addition, we are also including the responses to the labeling deficiencies.

For ease of review we have arranged the amendment as follows:

1. Form FDA 356h
2. Table of Contents
3. Table of Attachments
4. CMC: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses
5. Field Copy Certification
6. Labeling Responses

We have provided an archival copy, a review copy and a field copy for this response. We are looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (732) 465-3888
Fax: (732) 465-3885

MM 10/3/01

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

January 5, 2001

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855 - 2773

NEW CORRESP
NC

Re: Abbreviated New Drug Application (ANDA)
Milrinone Lactate Injection, 1 mg/mL, 50 mL vials

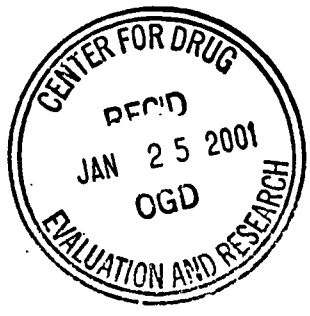
Abbreviated New Drug Application (ANDA # 75-830)
Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL vials

Dear Mr. Buehler:

Reference is made to Faulding's abbreviated new drug application for Milrinone Lactate Injection, 1 mg/mL, 50 mL Vials submitted to the FDA on December 1, 2000. Reference is also made to the telephone discussion with Ms. Emily Thomas, Regulatory Support, FDA on January 3, 2000.

During the discussion, Ms. Thomas indicated that Faulding should withdraw this application since the formulation and analytical methods used in this ANDA are same as the ANDA for Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL Vials (ANDA # 75-830) currently under review with the FDA. Ms. Thomas also indicated that we should file this new presentation as an amendment to the ANDA # 75-830 since the vial size (50 mL vial presentation) is the only difference.

Therefore, in accordance with the provisions of 21CFR 314.150 (c), Faulding Pharmaceutical Co. hereby requests the withdrawal of this ANDA, Milrinone Lactate Injection, 1 mg/mL, 50 mL Vials (ANDA #). As agreed with Ms. Thomas, we would also like to request that the paper ANDA already submitted to the FDA be treated as an amendment to the ANDA, Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL Vials (ANDA # 75-830).



We have included FDA Form 356h for both ANDAs, ANDA # _____ to request withdrawal of this ANDA and ANDA # 75-830 to request amendment to the application under review. A Field Copy Certification is also included with this submission. The field copy of this submission has been forwarded to FDA's San Juan District office.

We acknowledge that this request for withdrawal will be considered as a waiver of an opportunity for a hearing otherwise provided for in the relevant section of the regulations. Additionally, we understand that the agency will effect this withdrawal without prejudice to future filing.

Faulding Pharmaceutical Co. appreciates the agency's efforts in processing this request for withdrawal and awaits written confirmation regarding this action. Please call me at the phone number provided below if you need additional information regarding this submission.

Sincerely,

KPatel

Kala Patel, M.S., R.Ph.
Manager, Regulatory Affairs
Tel.: (908) 931- 3821
Fax.: (908) 709- 4150

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved : OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Faulding Pharmaceutical Co.	01/05/01
TELEPHONE NO. *(Include Area Code)* (908) 709-1200	FACSIMILE (FAX) Number *(Include Area Code)* (908) 709-4150
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: 11 Commerce Drive, Cranford, NJ 07016	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE: N/A

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued)

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Milrinone Lactate Injection	N/A

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)* 1,6-dihydro-2-methyl-6-oxo-[3,4'-bipyridinel]-5-carbonitrile lactate

CODE NAME *(If any)*: N/A

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Injection	1 mg/mL, 50 mL Vials	Intravenous

(PROPOSED) INDICATION(S) FOR USE: Indicated for the short-term intravenous therapy of congestive heart failure.

APPLICATION INFORMATION

APPLICATION TYPE (check one)

☐ NEW DRUG APPLICATION (21 CFR 314.50) ☒ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)

☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug	Holder of Approved Application
Primacor (Milrinone Lactate Injection)	Sanofi Pharmaceuticals, Inc.

TYPE OF SUBMISSION (check one)

☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION

☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT

☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

REASON FOR SUBMISSION: Withdrawal of the application

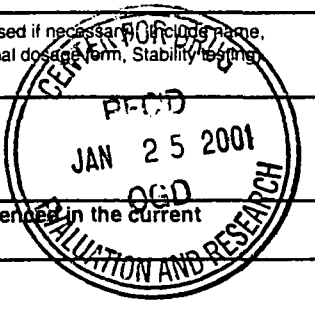
PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER-THE-COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED: 1

THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary) (include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.



Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs and DMFs referenced in the current application)

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

December 14, 2000

NEW CORRESP
Nc

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Original Application – Electronic Submission (EVA & Companion Document)

RE: Abbreviated New Drug Application
Milrinone Lactate Injection, 1 mg/mL, 50 mL vials

Dear Mr. Buehler:

Faulding Pharmaceutical Co. is submitting the electronic submission (EVA & Companion Document) for our Abbreviated New Drug Application (ANDA) for Milrinone Lactate Injection, 1 mg/mL, 50 mL vials, submitted on December 1, 2000.

In the cover letter, we had informed the agency that the application will include a CMC and bioequivalence ESD electronic submission. We have included a copy of the cover letter submitted with the original application.

The diskette containing the following information is provided with this correspondence:

1. CMC ESD submission
2. Companion Document Part 1
3. Companion Document Part 2

The composition of Faulding's Milrinone Lactate Injection, 1 mg/mL, 50 mL vials is qualitatively and quantitatively the same as the reference listed drug product, Primacor® Milrinone Lactate Injection, 1 mg/mL, 50 mL vial, manufactured by Sanofi Pharmaceuticals. Based on this information, Faulding has requested for a waiver of the in-vivo bioavailability/bioequivalence requirements. This electronic submission, therefore, does not contain a BA/BE ESD Submission.

Declaration

The information contained in the electronic submission (Milrinone Lactate Injection, 1 mg/mL, 50 mL vials, submitted on December 14, 2000) is not different from the information contained in the hard copy submission (Milrinone Lactate Injection, 1 mg/mL, 50 mL vials, submitted on December 1, 2000).

If you have any questions concerning this electronic submission, please contact Kala Patel, Manager, Regulatory Affairs at (908) 931-3821.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel: (908) 931-3806
Fax: (908) 709-4150

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

December 1, 2000

Mr. Gary Buehler, Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Original Application – Electronic Submission will be sent within 30 Days

RE: Abbreviated New Drug Application
Milrinone Lactate Injection, 1 mg/mL, 50 mL vials

Dear Mr. Buehler:

In accordance with the regulations, as promulgated under Section 505(j) of the Federal Food, Drug and Cosmetic Act, as amended, Faulding Pharmaceutical Co. is submitting this Abbreviated New Drug Application (ANDA) for Milrinone Lactate Injection, 1 mg/mL, 50 mL vials.

This application will include a CMC and bioequivalence ESD electronic submission. The diskettes will be sent as new correspondence within 30 days.

The reference listed drug Primacor® Milrinone Lactate Injection, 1 mg/mL is manufactured by Sanofi Pharmaceuticals in a 50 mL vial presentation. Milrinone Lactate Injection is an aqueous concentrated sterile solution for intravenous injection. The composition is qualitatively and quantitatively the same as the reference listed drug product.

Faulding has also submitted a separate ANDA for Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL Vials (ANDA # 75-830). The formulation for these presentations is same as the one for the 50 mL vials and the reference listed drug Primacor® Milrinone Lactate Injection, 1 mg/mL, manufactured by Sanofi Pharmaceuticals in 10 mL and 20 mL vials.

The Archival, Review, and Field copies of this Abbreviated New Drug Application have been prepared in accordance with the "Guidance for Industry on Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application". This application consists of three volumes and contains sterility assurance information. For ease of review, an additional copy of Section XXII, Sterilization Assurance Information and Data is provided as a separate volume.

Faulding is providing the Field Copy of this application to the San Juan District Office in accordance with 21 CFR 314.94.

If you have any questions concerning this submission, please contact me directly at (908) 931-3806.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel: (908) 931-3806
Fax: (908) 709-4150

Faulding
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VIA UPS OVERNIGHT COURIER

AMENDMENT TO MAJOR AMENDMENT SEPTEMBER 12, 2000

November 30, 2000

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

ORIG AMENDMENT
N/AC

RE: ANDA 75-830 – Milrinone Lactate Injection, 1 mg (base)/mL
10 mL and 20 mL Vials

Dear Mr. Buehler,

Faulding Pharmaceutical Co. would like to amend their response to the major deficiency response to FDA's letter received on September 12, 2000. The response was provided to FDA on November 22, 2000.

We would like to correct a mistake in our response to FDA's **Comment 6a** in which the agency requested an additional identification test for Lactate in Milrinone Lactate Injection. This method, provided in our response of November 22, 2000 in Attachment 10, erroneously identified the test method as *a* method and did not provide for the expected results under 5.0 Procedure, in the text. Unfortunately, this mistake was not discovered until after submission of the response. We are providing to you today the corrected copy of RD 2741 "Identification of Lactate in Milrinone Lactate Injection, 1 mg/mL".

The method validation package, provided to FDA's Philadelphia laboratory, did receive the correct copy.

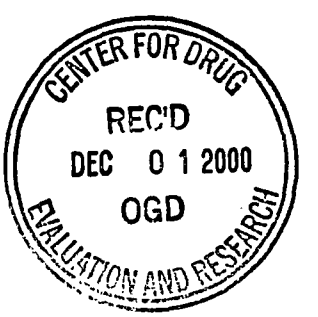
We are providing an archival copy, a review copy and a field copy of this correction to our submission of November 22, 2000.

Faulding sincerely apologizes for this error.

Yours Truly,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150



Faulding
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Facsimile (908) 709 4150

VIA FedEx OVERNIGHT COURIER

Major Amendment

November 28, 2000

ARCHIVAL COPY

Mr. Gary Buehler, Acting Director
FDA, CDER
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Amendment to Method Validation Package

NDA ORIG AMENDMENT
N/Ac

Re: ANDA Method Validation Amendment (ANDA # 75-830)
Milrinone Lactate Injection, 1 mg (base)/mL, 10 mL and 20 mL Vials

Dear Mr. Buehler:

In response to a major chemistry deficiency received on September 12, 2000 from the Food and Drug Administration, Center for Drug Evaluation, a number of methods have been added to our original submission and changes have been made in the drug substance and final drug product specifications. Faulding would like to amend the original Method Validation Package, submitted to the FDA Philadelphia Laboratory on October 5, 2000. The revisions in specifications and the new methods requested are listed in the table below. The response to the deficiency has been submitted to the FDA Center on November 22, 2000.

No.	Description	Method No.	Specification No.
1	Test Specifications: Milrinone Active Pharmaceutical Ingredient	---	
2	Test Specifications: Milrinone Lactate Injection, 1 mg/mL (Finished Product)	---	
3	Identification of Milrinone in Milrinone Lactate Injection, 1 mg/mL by UV	RD 2740	---
4	Identification of Lactate in Milrinone Lactate Injection, 1 mg/mL	RD 2741	---
5	Determination of Anhydrous Dextrose in Milrinone Lactate Injection, 1 mg/mL, by Polarimetry	RD 2739	---
6	Method Validation Report for Determination of Anhydrous Dextrose in Milrinone Lactate Injection 1 mg/mL by Polarimetry	Validation of RD 2739	---

Copies of the revised drug substance and drug product specifications are provided in **Attachment 1**. The new methods and the validation report are provided in **Attachment 2**.

This amendment to the Methods Validation Package is paginated consecutively in the bottom right corner of each page. Page numbers found in the center of each page provide information as to where this information is located in the amendment filed to our original ANDA on November 22, 2000, in response to FDA's deficiency letter of September 12, 2000.

If you require any additional information, please contact me at (908) 931-3806.

Sincerely,

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

Faulding
A World of Health

Faulding Pharmaceutical Co.
A subsidiary of Faulding Inc.
11 Commerce Drive
Cranford, New Jersey 07016
Telephone (908) 709 1200
Facsimile (908) 709 4150

VIA UPS OVERNIGHT COURIER

MAJOR AMENDMENT

November 22, 2000

Mr. Gary Buehler, Acting Director
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/AC

RE: ANDA 75-830 – Milrinone Lactate Injection, 1 mg (base)/mL
10 mL and 20 mL Vials

Dear Mr. Buehler,

Faulding Pharmaceutical Co. is responding to your deficiency letter dated September 12, 2000 in which you requested CHEMISTRY information and additional LABELING information.

For ease of review we have arranged the amendment as follows:

1. Form FDA 356h
2. Table of Contents
3. Table of Attachments
4. CMC: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses
5. Field Copy Certification
6. Labeling: Agency's comments, followed by Faulding's responses and any attachment(s) for the responses

We have provided an archival copy, a review copy and a field copy for this response. We are looking forward to your review of this Amendment.

Please contact me at the phone number provided below, if you need any additional information.

Sincerely,

H. Maaser

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel.: (908) 931-3806
Fax: (908) 709-4150

CENTER FOR DRUG EVALUATION AND RESEARCH
RECD
NOV 27 2000
OGD

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ack for S. Middleton 4/14/00 505(j)

labeling version drafted 4/26/00 A. Vezza

VIA UPS OVERNIGHT COURIER

March 31, 2000

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

RE: Abbreviated New Drug Application
Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL vials

Original Application

Dear Madam/Sir:

In accordance with the regulations, as promulgated under Section 505(j) of the Federal Food, Drug and Cosmetic Act, as amended, Faulding Pharmaceutical Co. is submitting this Abbreviated New Drug Application (ANDA) for Milrinone Lactate Injection, 1 mg/mL, 10 mL and 20 mL vials.

The reference listed drug Primacor® Milrinone Lactate Injection, 1 mg/mL is manufactured by Sanofi Pharmaceuticals in 10 mL and 20 mL vial presentations. Milrinone Lactate Injection is an aqueous concentrated sterile solution for intravenous injection. The composition is qualitatively and quantitatively the same as the reference listed drug product.

The Archival, Review, and Field copies of this Abbreviated New Drug Application have been prepared in accordance with the "Guidance for Industry on Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application". This application consists of four volumes and contains sterility assurance information. For ease of review, an additional copy of Section XXII, Sterilization Assurance Information and Data is provided as a separate volume.

Faulding is providing the Field Copy of this application to the San Juan District Office in accordance with 21 CFR 314.94.

If you have any questions concerning this submission, please contact me directly at (908) 931-3806.

Sincerely,

Heike Maaser, Ph.D.
Director, Regulatory Affairs
Tel: (908) 931-3806
Fax: (908) 709-4150