CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-855

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-855

Bristol-Myers Squibb
Attention: Susan H. Behling
Director, Regulatory Science
Pharmaceutical Research Institute
5 Research Parkway
Wallingford, CT 06492

Dear Ms. Behling:

Reference is made to your correspondence dated July 19, 2001, requesting a waiver for pediatric studies under 21 CFR 314.55(c).

We have reviewed the information you have submitted and agree that a waiver is justified for Mesnex® Tablets for prevention of ifosfamide-induced hemorrhagic cystitis for the pediatric population.

Accordingly, a waiver for pediatric studies for this application is granted under 21 CFR 314.55 at this time.

If you have questions, please contact Debbie Vause, Regulatory Project Manager, at (301) 594-5724.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur
8/14/01 04:59:53 PM

Vause, Debra

From: Martin, Alison
Sent: Wednesday, March 20, 2002 6:49 PM
To: 'susan.behling@bms.com'
Cc: Vause, Debra
Subject: Proposed drug approval announcement

Dear. Ms. Behling,

Two items we need to finalize with you at this late hour.

1. Our division has an arrangement with ASCO and ONS to email drug approval announcements on the day of approval. In this way, health care providers are immediately prepared to answer any immediate questions from patients. We would like you to review the attachment and see if it is acceptable to you. Please let Debbie know as soon as possible.

2. There has been one minor revision to the label. The first sentence under clinical trials for oral mesna is clarified by adding that ifosfamide was given concurrently. Specifically, it now reads, "Clinical studies comparing recommended intravenous and oral mesna dosing regimens demonstrated incidences of grade 3-4 hematuria of < 5% in both arms when used in conjunction with ifosfamice 1.2-2.0 gm/m2 for 3-5 days."

Is this acceptable? Also, I believe you are checking on whether the SCHEEF reference in the clinical trial section was 0/9 or 0/8.

Thank you for your assistance. Please feel free to contact Debbie and me with regard to these issues.

Alison Martin, M.D.

Mesna.announcement.
doc

Was there an answer to this? the date in 4th P of

You still left letter!

NDA ORIG AMENDMENT

BC

DUPLICATE

February 23, 1998

ASTA Medica, Inc.
Continental Plaza
401 Hackensack Ave.
Hackensack, NJ 07601

UNITED STATES OF AMERICA

Telephone (201) 525-2680
Telefax (201) 488-8595

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Review I
HFD 150
1451 Rockville Pike
Rockville, MD 20857

Attention: Robert DeLap, MD, Director
Division of Oncology Drug Products

6 1998

Re: Mesnex® (mesna) Tablets
NDA #20,855
Chemistry, Manufacturing and Controls Amendment

Dear Dr. DeLap:

Reference is made to our NDA for Mesna Tablets received by FDA on March 25, 1997 and to the February 23, 1998 fax from the Division requesting that we withdraw the original Environmental Assessment Section and replace it with a claim for categorical exclusion under 21 CFR section 25.31(a). The purpose of this submission is to comply with this request.

ASTA Medica, Inc. requests that the Environmental Assessment provided in Section d IV Volume /page 6/001 of our original NDA submission be withdrawn.

As indicated in the Federal Register Notice Final Rule (Volume 62, Number 145) published July 29, 1997 and effective August 28, 1997, we would like to claim a categorical exclusion under 21 CFR section 25.31(a). This request for categorical exclusion is included in this amendment.

If you have any questions or require any additional information or clarifications, please feel free to contact me.

Sincerely,

Aileen Ryan
Vice President
Regulatory Affairs and Compliance

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NEW DRUG APPLICATION
FD FORM 356H
SECTION d

MESNA TABLETS

CHEMISTRY, MANUFACTURING AND CONTROLS

Title: **IV. Environmental Impact Analysis Report**

Request for Categorical Exclusion

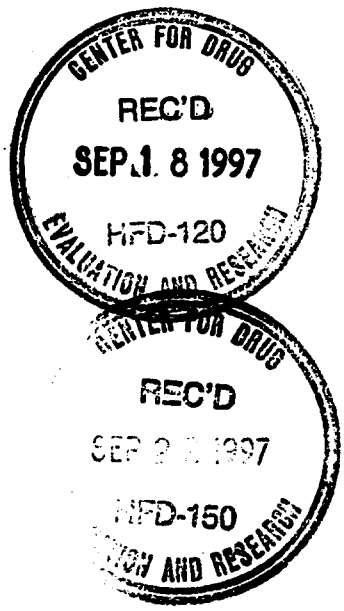
The requested action, approval of NDA 20-855, qualifies for a categorical exclusion from the requirement to prepare an environmental assessment under 21 CFR 25.31(b). To the knowledge of ASTA Medica, Inc., no extraordinary circumstances exist that would warrant the preparation of an environmental assessment.

Aileen Ryan
Vice President
Regulatory Affairs and Compliance

ORIGINAL

NDA ORIG AMENDMENT (BL)

September 17, 1997



ASTA MEDICA

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UNITED STATES OF AMERICA

Telephone (201) 525-2680
Telefax (201) 488-8595

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Review I
HFD 150
1451 Rockville Pike
Rockville, MD 20857

Attention: Leslie Vaccari
Division of Oncology Drug Products

Re: Mesnex® (mesna) Tablets
NDA #20,855

Dear Leslie:

As you had previously requested, enclosed are two (2) copies of the labeling for the blister strips and the box for the mesna tablets.

Sincerely,

Aileen Ryan

Aileen Ryan
Vice President
Regulatory Affairs & Compliance

Enclosure

E:\ARy\AILEEN.DOC\MESNA\usnda\ar091797lvd.doc

2 pages redacted from this section of the approval package consisted of draft labeling