

(3-9-92)

MEMORANDUM:

SUBJECT: Reregistration of Momosodium Methanearsonate (MSMA).
ISK-Biotech Corporation. Product Chemistry {Guideline
61.1}.
[DEB No.: 9447; ~~MRID 421535-01~~; DP Barcode: D174702]

FROM: Dennis McNeilly, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division [H7509C]

THRU: Francis B. Suhre, Section Head
Special Review Section II
Chemistry Branch II.- Reregistration Support
Health Effects Division [H7509C]

TO: Betty Crompton, PMT-51
Reregistration Branch
Special Review and Reregistration Division [H7508W]

Background

ISK-Biotech Corporation (formerly Fermenta ASC Corporation) has submitted a Confidential Statement of Formulation (CSF) for ANSAR 6.6. The Phase 4 Review (C. Olinger, 3/26/91) indicated that a CSF was not submitted. SRRD has asked CBRS to verify that this submission satisfies all series 61 and 62 data requirements

Discussion

The Phase 4 Review (C. Olinger, 3/26/91) cited two deficiencies pertaining to MSMA Product Identity (Series 61) and Analysis and Certification of Product Ingredients (Series 62) for ANSAR 6.6. ISK-Biotech has previously corrected one of these deficiencies concerning operating parameters in the manufacturing process (S. Funk, 1/13/92). Therefore the only series 61 or 62 data

deficiency for ISK-Biotech's MSMA product is the submission of a current CSF.

CBRS has reviewed the submitted Confidential Statement of Formulation (CSF). The CSF is acceptable to CBRS with the following exception: the CAS number for the active ingredient was not provided. CBRS has added the CAS # to the CSF and has attached a copy for your use (Attachment 1, CBI).

Conclusions and Recommendations

The data gaps identified under Guideline 61-1 in the Phase 4 Review of ISK-Biotech's MSMA product is satisfied provided SRRD accepts the CSF as modified by CBRS, i.e., adding the CAS # for the active ingredient. Therefore, all Series 61 and 62 requirements for ISK-Biotech's MSMA are satisfied.

There continue to be outstanding series 63 requirements as discussed in detail in CBRS's Phase 4 Review of ISK-Biotech's MSMA submissions.

NOTE: The registrant should be informed that in future submissions, the CAS # for each active ingredient and, if available, for each intentionally added inert material must be provided on the CSF.

ATTACHMENT 1: Revised CSF (CBI)

CC (with Confidential Attachment):Reviewer;MSMA List B file;
PMSD/PIB(C.Furlow).

CC (without Confidential Attachment):Circulation;RF;SF.

RDI: FBS,3/5/92;MSM,3/9/92;EZ,3/9/92.

H7509C: DMM;dmm;CM-2;Rm 800D;X305-5934;03/05/92

2