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APPLICATION NUMBER:

21-092

PHARMACOLOGY REVIEW

HFD-5-J
J. Fritsch

NOV 29 1999

PHARMACOLOGY / TOXICOLOGY REVIEW AND EVALUATION

NDA#: 21-092
Serial No.: 000
Type: Original NDA Submission – Nonclinical Pharmacology and Toxicology
Date of Submission: 3/19/99

Review Division: Special Pathogen and Immunologic Drug Products
HFD-590
Reviewer: Stephen G. Hundley, Ph.D., Pharmacologist
Review Completion Date: 11/29/99

Sponsor: Metabolic Solutions, Inc.
460 Amherst Street
Nashua, NH 03063

Phone Number: 603-598-6960

Drug Information

Name:	Helicosol™
Product Name:	Helicosol/device Ez-HBT Helicobacter Blood Test
Chemical Name:	^{13}C-Urea
CAS#:	58069-82-2
Molecular Formula:	$(NH_2)_2\ ^{13}CO$
Molecular Weight:	61.06 – 61.36
Chemical Formula:	$H_2N^{13}CONH_2$

Drug Category: Diagnostic Medical Device
Related Submissions: Not Applicable

Indication: Diagnosis of *Helicobacter pylori* in the gastrointestinal tract

BACKGROUND

The proposed drug product is a diagnostic medical device designed to detect the presence of *Helicobacter pylori* in the gastrointestinal tract. The patient will orally take a solution containing 125 mg of ^{13}C-urea. A blood sample will be drawn at a set time after drinking the solution and assayed for the ratio of $^{13}CO_2$ to CO_2. The scientific rationale is based upon the conversion by *H. pylori* of urea to CO_2 and NH_2 in the stomach via urease enzyme activity. If *H. pylori* is not present in the stomach the conversion of orally administered urea occurs only to a minor degree. A substantial amount of the $^{13}CO_2$ formed from ^{13}C-urea is absorbed from the stomach into the blood stream and can be measured by mass spectrometry.

There is no therapeutic activity associated with ^{13}C-urea in this administration regimen. Oral administration of 125 mg ^{13}C-urea has no pharmacologic or toxicologic activity. The stable isotope ,^{13}C, has no toxicologic properties and urea is a normal biochemical constituent in mammalian systems and is in much higher levels in humans than presented by the 125 mg oral dose. The sponsor cites and provides pertinent literature to this effect in the submission. There are no nonclinical pharmacology / toxicology reports in this submission for critical review.

EVALUATION

There are no pharmacology / toxicology issues presented in this submission.

/S/ 11/29/99
Stephen G. Hundley, Ph.D.

Concurrences:
HFD-590 / R.Albrecht / DDDir /S/ 11/30/99
HFD-590 / K. Hastings / TL /S/ 11/29/99
Disk:
HFD-590 / K. Hastings

cc:
HFD-590 / Original NDA
HFD-590 / Division File
HFD-345
HFD-590/ PM / J. Fritsch
HFD-590 / MO / R. Hopkins
HFD-590 / Biopharm / J. Meyer
HFD-590 / Pharm / S. Hundley
HFD-590 / Micro
HFD-590 / Chem
HFD-590 / Stat / K. Higgins