CHAPTER 7. PREGESTIMIL

7.1 Schedule of Supplementation

- When the total bilirubin is ≥1.5 mg/dL and the child is less than 12 months of age, Medium Chain Triglyceride (MCT)-containing formula (Pregestimil) or breast milk should be used, as long as the child's growth is "adequate". MCT-containing formula will be continued until 24 months of age if the total bilirubin is ≥1.5 mg/dL and the child is over 12 months of age.
- When the total bilirubin is <1.5 mg/dL, the child can be transitioned to standard infant formula (if <1 year of age) and whole milk (if ≥1 year of age).
- When growth is inadequate, measures will be taken for nutritional rehabilitation according to medical management used at each Childhood Liver Disease Research and Education Network (ChiLDREN) study site.

7.2 Receiving/Shipment Schedule

To receive a supply of Pregestimil, the study site should contact Rhonda Wood, 812-429-7716 or rhonda.wood@mjn.com. Shipments arrive in 5-10 working days.

Pregestimil is being supplied to all study sites at no charge; therefore Mead Johnson will not be utilizing purchase orders. Mead Johnson will include paperwork with each shipment that contains the person's name to which it should be delivered. Dr. Sokol has supplied Mead Johnson with these names and addresses.

For future shipments requested by study sites, notify study site receiving department that additional formula is expected in 5-10 working days from Mead Johnson.

7.3 Dispensing

When dispensing formula for the subject's parent(s) or legal guardian(s), the study site will need to document what is given to the subject on the Pregestimil Log (see Appendix **A**), including:

- Date dispensed.
- Subject ID.
- Number of cases dispensed.
- Lot number.
- Expiration date.

7.4 Sterility

The subject's parents or legal guardian(s) will require instruction on reconstitution of Pregestimil, only as much as is to be used at a specific time. The study site should inform the subject's parent(s) or legal guardian(s) using the Pregestimil to make each bottle fresh. Once the bottle is made, it should be kept refrigerated and discarded if not used within 24 hours of preparation.

7.5 Returning Formula to Mead Johnson

Mead Johnson arranges for pick-up of the Pregestimil from the study sites and return to Mead Johnson for destruction. This formula cannot be returned to inventory. Prior to requesting pick-up, please contact Dr. Sokol for guidance on appropriate use of the excess formula.

If the final result is for pick-up, return and destruction of the product, contact Rhonda Wood, 812-429-7716 or rhonda.wood@mjn.com.

7.6 Damaged or Expired Formula

If study sites receive damaged formula, notify Rhonda Wood, 812-429-7716 or rhonda.wood@mjn.com of the quantity required for replacement. The study site should dispose of the damaged product in a manner that prevents further human consumption.

In certain circumstances, the degree of damage may still permit for dispensing of the product at the study site. If the study site continues to receive damaged product, call Rhonda to discuss resolution of the issue with the shipping company.

Damaged or expired product can either be disposed of at the study site or returned to Mead Johnson.

- If destroying the formula onsite, each can should be opened and the contents discarded in such a manner as to prevent human consumption.
- If returning the formula to Mead Johnson for destruction, contact Rhonda Wood.

7.7 Contacts

For shipping/receiving issues contact:
Rhonda Wood
Mead Johnson Nutritionals
2400 West Lloyd Expressway
Evansville IN 47721-0001
Phone: (812) 429-7716
Email: rhonda.wood@mjn.com

For other issues contact:
Kimberly Merkel, RPh
Manager, Contracted Clinical Services
Mead Johnson Nutritionals
2400 West Lloyd Expressway
Evansville IN 47721-0001

Phone: (812) 429-7881
Fax: (812) 429-5925
Email: kim.merkel@bms.com

Appendix A: Pregestimil Log

STUDY SITE NUMBER: _____

A Randomized, Double-Blinded, Placebo-Controlled Trial of Corticosteroid Therapy Following Portoenterostomy in Infants with Biliary Atresia.

Date:	P004 Subject Number	# Cases Dispensed	Lot #	Expiration Date	Staff Intials