

Chapter 16

INTERVENTION MANUFACTURER'S PROCEDURES

AREDS is supported in part by Bausch & Lomb Pharmaceuticals. Bausch & Lomb will supply AREDS with study tablets for the run-in period (placebo), for the clinical trial (placebo, antioxidants, zinc, antioxidant and zinc), and Centrum[®]. The placebo tablets supplied for the run-in period will be labeled Trial Medication: Week 1—Week 4. The study medication tablets supplied for the clinical trial (placebo, antioxidants, zinc and antioxidants and zinc) will be labeled Study Medication. The study medication tablets will be identical in appearance, size, smell, and taste.

16.1 MANUFACTURING PROCEDURES

Specific procedures for the manufacturing of the AREDS study tablets including quality control measures and stability testing were submitted to the FDA in the IND for AREDS. This information is confidential.

16.2 SHIPMENTS TO THE DRUG DISTRIBUTION CENTER

Bausch & Lomb will ship bulk containers of study tablets and 100-tablet bottles of Centrum[®] to the Drug Distribution Center. Sufficient tablets will be shipped to package a 1-year supply of medication. Shipments will contain one lot number for each type of tablet and bulk containers will be marked with the name and strength of the agent, lot number, expiration date (if applicable), quantity, and manufacturer's name and address. Documentation summarizing the total amount of each medication in the shipment and the other information required on each container will accompany the shipment.