

Chapter 17

INTERVENTION PACKAGING AND DISTRIBUTION PROCEDURES

The United States Public Health Service (PHS) Supply Service Center located in Perry Point, Maryland will serve as the Drug Distribution Center for AREDS and will be responsible for:

- ! receipt and handling of study tablets and Centrum[®]
- ! packaging of study tablets
- ! distribution of study tablets and Centrum[®] to the Clinical Centers

17.1 RECEIPT AND HANDLING AND STUDY TABLETS AND CENTRUM[®]

The PHS Supply Service Center will receive, inspect, and store bulk containers of the AREDS study tablets and bottled Centrum[®]. The labeled containers will be stored until they are packaged and shipped, expire or are no longer needed, at which time they will be returned to Bausch & Lomb. A computerized perpetual inventory record of the quantity on-hand of each of the AREDS study tablets and Centrum[®] will be maintained.

17.2 PACKAGING OF STUDY TABLETS

All AREDS tablets will be packaged into high density poly-ethylene (HDPE) plastic unit-of-use containers, with plain (non child-resistant) closures. The tablets to be used for the run-in will be study placebo and will be packaged in bottles labeled "Trial Medication". The tablets to be used in the clinical trial will be placebo or contain minerals, antioxidants, or both minerals and antioxidants. The Coordinating Center will supply the PHS Supply Service Center with 50 bottle numbers and the tablet type assigned to these bottle numbers. Coded labels will be printed and attached to each bottle identifying the bottle number (01-50) and instructions for use. Packaging will be performed in separate runs for each bottle number (Study Medication) or type (Trial Medication) and lot number. Centrum[®] will be provided by Bausch & Lomb in pre-labeled bottles and will not require repackaging. Bottle codes 51 - 54 were added in 1996 for use by smokers who elected reassignment from beta-carotene.

17.3 DISTRIBUTION OF STUDY TABLETS

Three shipments will be made automatically by the Drug Distribution Center. The first shipment will contain a complete supply of run-in tablets, labeled "Trial Medication" and a 6-month supply of Centrum®. This shipment will arrive prior to Phase II initiation. The second shipment will contain 50 cases of study supplements, labeled "Study Medication" and will be delivered 3 to 4 months after Phase II initiation. The third shipment will be delivered approximately 6 months later and will contain 50 cases of Study Medications and another 6-month supply of Centrum®. Subsequent shipments of Study Medication and Centrum® will be requested by the AREDS Clinical Centers using the AREDS Supplement Order form.