

**DIPHTHERIA ANTITOXIN (DAT)**

The Meningitis and Vaccine Preventable Diseases Branch, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, CDC and the CDC Drug Services unit are providing diphtheria antitoxin under an Investigational New Drug (IND) protocol registered with the FDA (No. 6937). The data collection forms are an integral part of the IND; analysis of this data is crucial to monitoring adverse events and clinical effectiveness. Your cooperation is greatly appreciated. If you have any additional questions about any aspects of the protocol, you can contact the CDC diphtheria duty epidemiologist through the Director's Emergency Operations Center (DEOC) at 770-488-7100. Included in this packet are:

1. The drug you requested from the Centers for Diseases Control Drug Service. If the drug is not used for the patient for whom it was requested, it must be returned to the address listed below or the Quarantine Station that shipped the drug. If you wish to use the drug in another patient please notify the CDC diphtheria duty epidemiologist immediately.
2. Informational Material for the accompanying drug
3. Form FDA-1572 for Clinical Investigators. It is a Food and Drug Administration (FDA) requirement that each physician using this drug file to be a Clinical Investigator. By signing the form FDA-1572, the clinical investigator assures that the requirements set forth in 21CFR56 will be met.
4. Patient Consent Statement. Please complete this statement and arrange for the patient or guardian to read and sign it. A copy of this form should be given to the patient and a copy should be maintained in your patient's file.
5. Patient Reports. We are obligated, under the provisions of our Investigational New Drug (IND) permit, to obtain clinical information on each of the patients treated with this drug. Please complete and forward these reports (DAT Treatment and Adverse Effects, CDC Diphtheria Worksheet, Information for Close Contacts DAT), a signed FDA-1572, and a current curriculum vitae to the CDC Drug Service upon completion of therapy. Reports are considered "past due" 30 days after the drug has been administered.

All Forms should be returned to: CDC Drug Service D09, 1600 Clifton Road, Atlanta, GA 30333
Telephone: 404-639-3670 FAX: 404-639-3717

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This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/vpd-vac/diphtheria/dat/downloads/dat-cvr-letter.pdf>