Records Schedule Number: DAA-0512-2024-0004

Status: APPROVED
Date Approved: 12/19/2024

General Information

Agency or Establishment	Health Resources and Services Administration
Record/Scheduling Group	0512 - Records of the Health Resources and Services Administration
Records Schedule Applies To	Agency Subdivision
Major Subdivision	Office of the Associate Administrator
Minor Subdivision	Health System Bureau
Schedule Subject	Clofazimine Clinical Trial Record
Additional Schedule Information	Clofazimine is a drug approved by the Food and Drug Administration (FDA) for the treatment of lepromatous leprosy, including dapsone-resistant lepromatous leprosy and lepromatous leprosy complicated by erythema nodosum; the drug is only available in the USA for use in leprosy only through an “Investigational New Drug” (IND) status requiring informed consent and Institutional Review Board (IRB) approval. The Centers for Disease Control (CDC) IRB is the Central IRB for this protocol. Healthcare providers wishing to obtain Clofazimine for leprosy patients must apply through the National Hansen’s Disease Program to be approved co-investigators under the IND of Clofazimine Use in the Long-Term Treatment of Leprosy
Is There a Classified Version of This Schedule?	No
Is consultation and coordination with Tribal Governments required?	No - the records covered by this schedule do not implicate Tribal interests

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Item Count

Total number of disposition items: 1
Number of Temporary disposition items: 1
Number of Permanent disposition items: 0
Number of Items with Disposition Not Approved: 0
Number of Inactive disposition items: 0

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Outline of Records Schedule Items for DAA-0512-2024-0004

Item #	Title	Disposition
0001	Clinical Study of Clofazimine for use in the Long-Term Treatment of Leprosy	Temporary

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Records Schedule Items

DAA-0512-2024-0004-0001	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Clinical Study of Clofazimine for use in the Long-Term Treatment of Leprosy
Item Description	These records pertain to the clinical study of Clofazimine for treating Leprosy, which the National Hansen's Disease Program sponsors. These files consist of the Food and Drug Administration (FDA), Investigational New Drug (IND) application, associated documents of communication with the FDA, and the application submitted for approval to ensure the safety and rights of the subjects and assurance of the drug's effectiveness and safety.
Item Description	Physicians must apply to become co-investigators in the study; application forms and a curriculum vitae (CV) are required. The patient enrollment forms for the study undergo a meticulous process, ensuring the highest data collection standards. This includes gathering patient demographics and medical information, a crucial step in ensuring the accuracy and comprehensiveness of study data. To be involved in the study, patients must sign consent forms that emphasize the importance of patient rights and safety. Drug accountability investigators must maintain a detailed drug accountability record, ensuring the utmost care and responsibility in drug management. The form is included with each shipment of the drug. Since the FDA requires a disposition record under this investigational protocol, this record must be returned with each request for an additional supply.
Item Description	

	The Centers for Disease Control (CDC) and Investigation Review Board (IRB) play a crucial role in the study, ensuring the study's adherence to regulatory standards. An annual study protocol review is required to prove it is consistent with FDA regulations and guidance. This underscores our commitment to regulatory standards and the continuous monitoring of the study's progress. A requirement of the IND is annual reporting to the FDA, including the number of subjects enrolled under the IND tabulated by age, group, gender, and race, as well as patient response to treatment and side effects, Novartis Pharmaceutical order requests, and associated communications documents. Novartis is the drug supplier. Order requests are for additional supplies of the drug, emphasizing the need for regular and transparent communication with all stakeholders.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cut off annually at end of year.
Retention Period	Other: Destroy 2 years after the study is closed.
ADDITIONAL INFORMATION	
Legal citation related to record retention (if applicable)	n/a
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

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Signatory Information

Action	User	Date
Approve	Colleen Shogan	12/19/2024