

MEMORANDUM

FOOD AND DRUG ADMINISTRATION,
October 8, 1970.

To: All medical officers, Bureau of Drugs.

From: Marvin Siefe, M.D., Acting Director, Office of Scientific Evaluation,
Bureau of Drugs.

Subject: "Disqualified" clinical investigators.

1. This updates Dr. Simmons' memo of May 20, 1970 on the same subject.
2. The following physicians are not eligible to receive investigational use drugs. Studies should not be performed by these physicians after their date of disqualification and if such studies are observed in support of IND's NDA's, Form 5's or supplements they should be brought to the attention of the office director and follow-up initiated. In the absence of evidence validating their work, data from these individuals, regardless of date cannot be considered reliable to support safety or efficacy claims in IND's, NDA's, supplements, or Form 5's.

NAME OF INVESTIGATOR AND DATE OF DISQUALIFICATION

William Abruzzi, M.D., Wappingers Falls, N.Y., August 31, 1966.
 Sheldon Bender, M.D., Philadelphia, Pa., February 17, 1969.
 Leo Cass, M.D., Cambridge, Mass., December 15, 1965.
 DCF Research, Inc., New York, N.Y., October 18, 1966.
 Edwin Dunlop, M.D., Attleboro, Mass., February 16, 1970.
 Anthony Lapolla, M.D., Camarillo, Calif., May 5, 1969.
 Leo Loewe, Brooklyn, N.Y., October 18, 1966.
 Kathleen Roberts, M.D., Owego, N.Y., November 24, 1964.
 Bennett Robin, M.D., Silver Spring, Md., June 19, 1964.
 Wallace Rubin, M.D., New Orleans, La., March 13, 1970.
 Harry Shubin, M.D., Philadelphia, Pa., March 16, 1970.
 Joseph J. Sobotka, M.D., Phoenix, Ariz., September 21, 1970.
 Samuel Splitter, M.D., Hempstead, N.Y., July 29, 1968.

3. The four physicians listed below have at one time been ineligible to receive investigational-use drugs but have been reinstated as eligible. Work performed subsequent to reinstatement is acceptable for evaluation. Work performed prior to reinstatement, in absence of validating evidence, cannot be considered in support of safety or efficacy claims in IND's, NDA's, supplements, or Form 5's.

NAME OF INVESTIGATOR AND DATE OF REINSTATEMENT

Charles Carter, M.D., Orlando, Fla., July 29, 1969.
 Herbert Copelan, M.D., Philadelphia, Pa., August 19, 1966.
 Albert Kligman, M.D., Philadelphia, Pa., August 19, 1966.
 Gordon McHardy, M.D., New Orleans, La., January 27, 1969.

4. Investigations of the work of clinical investigators are conducted and coordinated by the Scientific Investigations Group of the Office of Scientific Evaluation. It is requested that all suspicions concerning validity of a physician's work with investigational drugs be communicated informally to SIG (BD-108, Room 14B-31, Ext. 31727).

5. Regulations relative to the "disqualification" of investigators may be found in Section 130.3(c) of the New Drug Regulations as found in Title 21 CFR (page 11 in the January 1, 1970, Revision).

6. Disqualification of investigators is one of the most serious actions that we take. For this reason, we make every effort, as provided in our regulations, to give an investigator an opportunity to explain deficiencies that we encounter in his studies. In addition, an action to disqualify is only disseminated to other sponsors or applicants who have previously used the services of the investigator and to interested government agencies. When and if a criminal action is filed against an investigator for submitting false data, it then becomes public information.