DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 0 6 2009

By Certified Mail - Return Receipt Requested

Charles E. Runels, Jr., M.D.
750 Downtowner Loop West
Mobile, Alabama 36609-5528

Notice of Disqualification of Eligibility to Receive Investigational Drugs

Dear Dr. Runels:

I have reviewed the administrative record of the regulatory proceeding proposing to disqualify you from eligibility to receive investigational new drugs. Based upon my review, I have concluded that there is no genuine and substantial issue of fact with regard to whether you repeatedly or deliberately violated Title 21, Code of Federal Regulations (CFR) Part 312 in connection with an investigational new drug study of a smallpox vaccine. Consistent with 21 CFR 312.70(b), and under authority delegated to me by the Commissioner of Food and Drugs, I am issuing this Commissioner's Decision disqualifying you from eligibility to receive investigational new drugs.

By this letter, I am providing a copy of this Decision to counsel for the Center for Biologics Evaluation and Research and to the Division of Dockets Management to be placed on display in the public reading room, and posted on FDA's website.

You may seek to have your eligibility to receive investigational new drugs reinstated pursuant to 21 CFR 312.70(f), upon presentation of adequate assurances that you will employ investigational drugs solely in compliance with the provisions of 21 CFR Parts 50, 56, and 312.

Sincerely,

Norris E. Alderson, Ph.D.
Associate Commissioner for Science

Enclosure

cc: Nancy Stade, Esq.
Counsel for the Center for Biologics Evaluation and Research, FDA

Division of Dockets Management