

Dear Sir or Madam:

We write to inform you that certain user account information for users of the Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) On-Line submission system was recently compromised. On October 15, 2013, the agency detected an unauthorized network access that obtained user account information consisting of each user's first and last name, the phone number and e-mail address associated with each account, and the username and password for each account. The agency temporarily disabled the system, immediately implemented corrective security measures, and administered password resets, as was communicated by email on October 18 to active account holders. The agency has confirmed that no system data has been altered, and we are continuing our analysis to confirm that there have been no unauthorized logins to the system.

To protect yourself against the potential malicious use of the compromised information (e.g., attempted identity theft or fraud) we recommend that you not use the compromised username or password with any of your online accounts.

If you have on-line accounts for which you have used the compromised password or username we recommend you immediately change that password or username and monitor those accounts for unauthorized activity. If this includes financial accounts, you may wish to place an initial fraud alert on your credit account. You may do so by contacting one of the three credit reporting companies. You need only call one company for all three to be alerted.

Equifax

800-525-6285

www.equifax.com

Experian

888-397-3742

www.experian.com

TransUnionCorp

800-680-7289

www.transunion.com

Even if you do not find any suspicious activity on your initial credit reports, we recommend that you check your credit reports periodically to help you spot potential problems and address them quickly.

Should you find suspicious activity on your credit reports or have reason to believe your information is being misused, immediately contact your local law enforcement to file a police report. It is recommended that you obtain a copy of the police report because many creditors want the information it contains to absolve you of fraudulent debts. When you decide to file a police report, it is also recommended that you file a complaint with the Federal Trade Commission (FTC) at www.ftc.gov/idtheft or at 1-877-ID-THEFT (877-438-4338) and inform FTC if you believe misuse of your information is related to this incident of unauthorized access to FDA's CBER On-Line system. Your complaint will be added to the FTC's Identity Theft Data Clearinghouse, where it will be accessible for law enforcement.

Please know the agency is committed to safeguarding the information you share with us. We will continue to monitor this matter and will make every effort to prevent the recurrence of this event.

If you have any questions regarding resetting your password, please call 800-835-4709 (or 301-827-1800) or send an email to industry.biologics@fda.hhs.gov.

Sincerely,

/S/

Robert A. Yetter, Ph.D.
Associate Director for Review Management
Center for Biologics Evaluation and Research