

From: OC GCP Questions
Sent: Friday, May 02, 2014 1:27 PM
To: [REDACTED]
Subject: RE: Questions Regarding The "Clinical Investigators - Disqualification Proceedings" Web Page

Dear [Redacted],

Thank you for your inquiry and for visiting our webpage at www.fda.gov/disqualificationproceedings. Your questions were forwarded to me for consideration. Below, please see my responses to your questions.

1. How often is this information updated?

We update the webpage every time there is new information. The information is posted as close to real time as possible. For example, Dr. Michael Dean Berger was disqualified on April 29, 2014. Before posting his updated status to "Disqualified", we must confirm that he received notice that he is disqualified. On May 1, 2014, we received that confirmation of delivery. Early on the next day, May 2, 2014 (today), the updated information is posted.

A delay in posting information may occur if we have difficulty locating an investigator to notify him or her about the disqualification proceeding or final action. New matters are added to the webpage when a Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE) letter is issued to an investigator and confirmation of delivery is received.

2. Is there a way that you let the public know when or if there is a change to the information or to the format of the information?

At the bottom of the database page at <http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true>, you can see "Page Last Updated". The update regarding Dr. Berger mentioned in the response to question 1 above resulted in this "Page Last Updated" date changing to "05/02/2014". You can check this field to see if any updates were entered since last viewing the webpage.

The current webpage format was consolidated from several separate webpages about investigator disqualification proceedings (e.g., there was a separate webpage for restricted investigators, reinstated investigators, etc.). The current consolidated webpage went live on October 31, 2012. To my knowledge, we have no plans to change the current format.

I hope this information is helpful to you. If further assistance is needed, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov.

Best regards,
Kathleen Pfaender, RN, JD
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of Medical Products and Tobacco

Federal Food and Drug Administration
WO32/5129
301-796-8346

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [Redacted]
Sent: Wednesday, April 30, 2014 8:17 PM
To: Kassim, Sean
Subject: Questions Regarding The" Clinical Investigators - Disqualification Proceedings" Web Page

Dear Mr. Kassim,

We spoke briefly a week or two ago, and you asked me to send you this email.

I work in [Redacted].

I produce a monthly [Redacted] report, that lists health care providers (usually MD's) who have run afoul of the Federal Government – often by Medicare fraud, prescription abuse, etc.

I get information from a number of web pages that are provided by various federal departments, which lists health care provider names and their current status.

This report is then used by our [Redacted] departments at our [Redacted] - to screen physicians.

One of the web pages from which I get my information is one that you are responsible for...

The title of this webpage is:

"Inspections, Compliance, Enforcement, and Criminal Investigations"

with the subtitle:

"Clinical Investigators - Disqualification Proceedings"

<http://www.fda.gov/ICECI/EnforcementActions/UCM321308>

There is a link at the bottom of this page:

[Clinical Investigator - Disqualification Proceedings Database](#)

that, when clicked, leads to the web page:

<http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true>

this web page has the header:

"Clinical Investigators - Disqualification Proceedings"

On this page is an Excel icon, which when clicked, brings up a spreadsheet with health provider information that I download for the Excluded Persons Report process.

I am currently gathering information for a report of the data sources that we use in regards to the frequency of data updating.

My two main questions are:

1. How often is this information updated?

Some of the federal office update their information on a monthly basis.

One office updates every day except Sunday and Monday.

Another FDA department updates their webpage every time there is new information (even though, officially, they are only required to update their webpage on a quarterly basis).

2. Is there a way that you let the public know when or if there is a change to the information or to the format of the information?

An example is OIG (Office of Inspector General), who made a number of changes last year and gave 3-months advance notice on their web site.

At this writing, only OIG has done this. Other web sites usually make format or content changes without notice.

Mr. Kassim, I look forward to your response.

Sincerely,

[Redacted]