

Brockner Ryan, Beth

From: Ball, Leslie
Sent: Monday, November 23, 1998 3:27 PM
To: Varricchio, Frederick
Cc: Ball, Robert; Pratt, Douglas R.
Subject: MedWatch reports for Thimerosal

Importance: High

Fred:

We're working on a FDAMA project involving mercury in drugs and biologics and need to query the MedWatch database for reports involving biologics containing mercury. We've already done this for vaccines in the VAERS database, using the search terms mercury, thimerosal, thiomersal and merthiolate. Our CDER colleagues on the FDAMA committee have performed a MedWatch query for drugs but specifically excluded biologics.

Bob Ball said you were the contact person to perform queries of the MedWatch database. We need information on reports to MedWatch for biologics using the search terms as outlined above. Bob or I can give you more specifics on the data we need. This needs to be performed for a report due in mid-January.

Thanks,

Leslie

rockner Ryan, Beth

From: Varricchio, Frederick
Sent: Tuesday, January 19, 1999 5:31 PM
To: Ball, Leslie
Subject: RE:

My plan is to get whatever is on the summary for every 100th report. We should have that in a couple of days. I'll let you know when it is here and we can see what to do next.

-----Original Message-----

From: Ball, Leslie
Sent: Thursday, January 07, 1999 11:10 AM
To: Varricchio, Frederick
Cc: Pratt, Douglas R.; Ball, Robert
Subject: RE:

Fred:

Are there 7000 reports just for immune globulins and other biologics? Drugs have been excluded? If there are real 7000 reports for biologics, perhaps you can get records on a subset of 50 or so we can look at them and get a general idea of what's been reported before we go any further. I'll be out of the office for Dr. Hardegrees party until 1:30 or later today, or I can discuss it with you tomorrow after 1 pm.

Leslie

-----Original Message-----

From: Varricchio, Frederick
Sent: Thursday, January 07, 1999 10:17 AM
To: Ball, Leslie
Subject:

I HAVE SOME RESULTS FOR YOU. PROBLEM IS THAT THERE ARE 7000 REPORTS THAT MENTION THIMERASOL. WHAT TO DO NOW. OBVIOUSLY LOOKING AT ALL 7000 IS A BRUTE FORCE APPROACH.

frederick varricchio