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**United States Senate**

COMMITTEE ON THE JUDICIARY  
WASHINGTON, DC 20510-6275

BRUCE A. COHEN, *Chief Counsel and Staff Director*  
KOLAN L. DAVIS, *Republican Chief Counsel and Staff Director*

July 24, 2012

**Via Electronic Transmission**

The Honorable Margaret A. Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD, 20993

Dear Commissioner Hamburg:

The recent exposure of approximately 80,000 pages of protected whistleblower communications by U.S. Food and Drug Administration (“FDA”) employees prompted my staff to look into the circumstances surrounding the release of the documents. Apparently, the FDA contracted with Quality Associates, Inc. to perform document management services, including the conversion of various files generated from spying on whistleblowers into portable document format (“PDF”) with unique numbering on each page in anticipation of use in litigation. However, the documents were made available to the public through an unsecure File Transfer Protocol (“FTP”) server operated by Quality Associates.

According to Quality Associates, the FDA files on its public FTP site were uploaded on May 3, 2012 and archived on May 9, 2012.<sup>1</sup> Further, according to Quality Associates, FDA did not indicate that the documents were sensitive or that they contained personally identifiable information (“PII”) under the Privacy Act. This claim appears to be supported by the official work order.<sup>2</sup> Although it is dated May 23, 2012,<sup>3</sup> two weeks after the work had already been done and two days after the “order” date listed on the Quality Associates invoice,<sup>4</sup> the official work order also communicates to Quality Associates that the documents are not classified, not sensitive but unclassified (“SBU”), and do not contain PII.<sup>5</sup>

In order to fully understand how this document release occurred, please respond to the following questions and provide related documentation:

1. Please provide and describe all communications to Quality Associates regarding the file converting contract, DHHS\FDA work order 69308.

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<sup>1</sup> Letter from Paul Swidersky, President, CEO, Quality Assocs., Inc., to Senator Charles Grassley, July 17, 2012.

<sup>2</sup> *Simplified Purchase Agreement Work Order Form 4044*, Work Order No. 69308, GPO, (Rev. Apr. 2010).

<sup>3</sup> *Id.*

<sup>4</sup> *Invoice*, No. 016000, QUALITY ASSOCS. INC. (June 4, 2012).

<sup>5</sup> *Simplified Purchase Agreement Work Order Form 4044*, Work Order No. 69308, GPO, (Rev. Apr. 2010).

2. Prior to May 23, 2012, did FDA represent to Quality Associates that the files submitted for conversion contained no information that was classified, SBU, or PII? Please describe all communications with Quality Associates regarding the nature of the documents to be converted and provide all records relating to those communications.
3. Why was Quality Associates allowed to begin work without an authorizing work order? Was the work completed on a rush basis, and if so why?
4. Please explain the timeline as to when Quality Associates actually performed services for the federal government. More specifically, please clarify how Quality Associates claims that the files were uploaded on May 3, archived on May 9,<sup>6</sup> the order was placed on May 21,<sup>7</sup> and the work order was approved May 23.<sup>8</sup>
5. Who was responsible for initiating the work order eventually received by Quality Associates? Please provide the originating document(s).
6. Were there any additional employees, either within FDA, the Government Printing Office (GPO), or any other federal agency responsible for passing along the details of the Quality Associates work order? Please provide the information about the documents related to all of the steps required from the originating document until the purchase agreement is considered complete.
7. Who was responsible for preparing the "Simplified Purchase Agreement Work Order Form 4044" for Quality Associates' DHHS\FDA work order no. 69308? Where did that person obtain the information contained within the document?
8. Does the FDA still maintain that the documents provided to Quality Associates contain no information that is classified, SBU, or defined as PII under the Privacy Act?
9. What litigation was this document conversion being prepared for? Were the documents being prepared for production or merely for review in order to determine what would and would not be produced?
10. Quality Associates asserts that the original files were initially supplied on physical media to another contractor. What is the name of the other contractor?
11. How many files were contained on the physical media?
12. What was the total number of pages provided from Quality Associates to FDA following the conversion?

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<sup>6</sup> Letter from Paul Swidersky, President, CEO, Quality Assocs., Inc., to Senator Charles Grassley, July 17, 2012.

<sup>7</sup> Invoice, No. 016000, QUALITY ASSOCS. INC. (June 4, 2012).

<sup>8</sup> *Simplified Purchase Agreement Work Order Form 4044*, Work Order No. 69308, GPO, (Rev. Apr. 2010).

Thank you in advance for your prompt attention to these matters. Please answer the previous questions and provide the requested documentation August 3, 2012. Should you have any questions, please contact Erika Smith of my staff at (202) 224-5225.

Sincerely,

A handwritten signature in blue ink that reads "Chuck Grassley". The signature is written in a cursive, flowing style.

Charles E. Grassley  
Ranking Member

# Attachment One

# QUALITY ASSOCIATES, INC.

## INVOICE

ORDER NUMBER:  
REQUISITION NUMBER:  
CONTRACT NUMBER:  
PROJECT NUMBER:  
ACCOUNT NUMBER:



INVOICE No.: 016000

Net Terms: Net 30

Period: May, 2012

ATTN: Office of the Comptroller  
U.S Government Printing Office  
STOP FMCS  
Washington, DC 20401

Date: June 04, 2012

Remittance Information: Payment by EFT, ACH or Wire Transfer  
Account Name: Quality Associates, Inc.  
Bank: The Columbia Bank, Columbia, MD  
Account

Payment by Check  
Quality Associates, Inc.  
12209 Benson Branch Road  
Ellicott City, MD 21042

Please make check payable to: Quality Associates, Inc.  
QAI Tax I.D.

Contact:

Description: See Attached

**TOTAL AMOUNT DUE = \$ 4,000.00**



**QUALITY  
ASSOCIATES  
INCORPORATED**

8161 Maple Lawn Blvd.  
2nd Floor  
Fulton, MD 20759  
Phone: (410) 884-9100  
Fax: (410) 884-9122

**INVOICE**

Invoice No. 016000  
Date 6/4/2012  
Quote No. QAI-2452-0512  
Customer ID 2452

**BILL TO:**

Office of the Comptroller  
U.S. Government Printing Office  
STOP FMCS  
Washington, DC 20401

**SHIP TO:**

Program Support Center - Dept of Health & Human Services  
Div. of Support Services  
5600 Fishers Lane, Room 3B-26  
Rockville, MD 20857

Contact: [REDACTED]

PAGE 1

PAYMENT TERMS		SHIP VIA	ORDERED BY	CUSTOMER P.O. NO.			
Net 30		Best way		96645			
ORDER DATE	PROJECT		SALES PERSON	PROJECT ID			
5/21/2012	PSC-HHS Dept DHHS-FDA Littigation File Orginazation - SPA			24525001			
ITEM #/ CLIN #	MODEL #	ITEM/MANUFACTURE	QTY ORDERED	UNITS	QTY SHIPPED	PRICE	EXT. PRICE
001	ISD Services	Analyze data from client supplied hard drive. Convert files from various formats to pdf for printing.	1.00		1.00	\$4,000.0000	\$4,000.00

**REMITTANCE INFORMATION**

**Payment by EFT, ACH or Wire Transfer**

Account Name: Quality Associates, Inc.  
Bank: The Columbia Bank, Columbia, MD  
Account [REDACTED]

**Payment by Check**

Quality Associates, Inc.  
12209 Benson Branch Road  
Ellicott City, MD 21042

Sales Total	\$4,000.00
Shipping & Handling	0.00
Misc. Charges	0.00
Tax Total	0.00
	<hr/> 4,000.00
Less Paid Amount	0.00
<b>TOTAL</b>	<b>\$4,000.00</b>

# Attachment Two

940 Invoice Documents

# Simplified Purchase Agreement Work Order Form 4044

You are hereby authorized to manufacture and ship the following described product in accordance with the purchase order and

QUOTES DUE BY

DEPARTMENT DHHS/FDA		REQ. NO. 2-06004-	JACKET NO. 372-628	SPA NO. 960	WORK ORDER NO. 69308
CLASSIFICATION Classified <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No SBU <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No PII <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		PUBLICATION TITLE LITIGATION FILE ORGINAZATION		DATE PREPARED 05/23/2012	OBJECT CLASS
CONTRACTOR Quality Associates Inc			PURCHASE ORDER NO. 96645	STATE CODE 190	CONTRACTOR'S CODE 72508
			SHIP/DELIVERY DATE 5/25/2012		
NOT FOR CONTRACTOR	BILLING ADDRESS CODE (BAC) 4164-01		AGENCY LOCATION CODE (ALC) 75060099		APPROPRIATION CHARGEABLE/OBLIGATION NO. 69999WC
	<input type="checkbox"/> Pay by Purchase Card		PURCHASE CARD NO. (Info to Appear on GPO Copy Only)		EXP. DATE
	PHONE NO. OF CARDHOLDER		EMAIL OF PURCHASE CARDHOLDER		TREASURY ACCOUNT SYMBOL (TAS)
	LINE OF ACCOUNTING REFERENCE NUMBER (Info Will Appear on IPAC as Entered) 2000061				
SPECIFICATIONS	PROOFS <input type="checkbox"/> Content (QTY) <input type="checkbox"/> Inkjet (QTY) <input type="checkbox"/> High Resolution (QTY) <input type="checkbox"/> Prior to Production Samples (QTY) <input type="checkbox"/> Electronic Soft Proof		DAYS DEPT. WILL HOLD PROOFS		QUALITY LEVEL
	FURNISHED ELECTRONIC MEDIA <input type="checkbox"/> Files to be sent via FTP or Email <input type="checkbox"/> CD/DVD (QTY)		OTHER GOVT. FURNISHED MATERIALS		PRESS SHEET INSPECTION <input type="checkbox"/> No. of Hours Notice
	COVER PAPER		COLOR OF COVER INKS	COVER COATING TYPE	PAPER COVERS (Self) (Separate)
	TEXT PAPER		COLOR OF TEXT INK	TEXT COATING TYPE	NUMBER OF TEXT PAGES 0
	STITCH <input type="checkbox"/> ULC <input type="checkbox"/> SIDE <input type="checkbox"/> SADDLE		BINDING <input type="checkbox"/> COMB <input type="checkbox"/> COIL <input type="checkbox"/> PERFECT BOUND <input type="checkbox"/> SEW <input type="checkbox"/> TAPE <input type="checkbox"/> TRIM 4 SIDES <input type="checkbox"/> OTHER		INDICATE WHICH COVERS PRINT 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/>
ADDITIONAL INFORMATION	Description Organize and bates number 69,000 files. Create pdfs and email to address supplied. Please send email to james.helton@psc.hhs.gov when job is delivered. GFM, Negs, Samples to JAMES HELTON, 6600 Fishers Lane, Parkawn Bldg. Room 3B-26, Rockville, MD 20857. 301-443-6740 **Delivery hours for the Parkawn Building are 8:00 am to 12:00 pm -- 1:00 pm to 4:00 pm. Deliveries must be made at loading dock.** All invoices are to be sent to: U.S. Government Printing Office, Office of the Comptroller, STOP FMCS, Washington, DC 20401 or faxed to 202-512-0992. Include program and work no. on labels to insure proper payment.				
	<input type="checkbox"/> Supplemental Information Attached				
DELIVERY	DELIVER PRODUCT TO:		RETURN FURNISHED MATERIAL TO:		
	<input type="checkbox"/> Distribution List Attached		Digital Deliverables Requested -Format: <input type="checkbox"/> Native <input type="checkbox"/> PDF		
SUPT. DOCS. NOTIFIED <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		SUPT. DOCS. QUANTITY ORDERED		SUPT. DOCS. DELIVERY ADDRESS	
CONTRACTOR TOTAL QUOTE \$4,000.00		SUPT. DOCS. COST		ADDITIONAL RATE	
FOR ADDITIONAL INFORMATION CONTACT:		EMAIL		PHONE NO.	
AUTHORIZING SIGNATURE (must be on file with GPO)				DATE SENT TO CONTRACTOR 5/23/2012	
ORDER RECEIVED BY: (Agency Representative)				DATE ORDER RECEIVED 5/23/2012	
CONTRACTOR INVOICE	All contractor invoices are to be FAXED to GPO at 202.512.1851. For instructions on how to prepare your bill and get paid go to <a href="http://www.gpo.gov/vendors/payment.htm">www.gpo.gov/vendors/payment.htm</a>				
	I certify that the materials/services ordered have been delivered on the date indicated above and that payment or credit has not been received. The penalty for making false statements to the Government is prescribed in 18 USC 1001.				
CONTRACTOR SIGNATURE		DATE			



Work Description, May 2012



Quality Associates, Inc.  
8161 Maple Lawn Blvd, 2nd Floor  
Maple Lawn, MD 20759  
Fax: 410-884-9122  
Tel: 410-884-9100



Provided To:

Printing Specialist, Pub Mgmt Branch  
Div of Support Services  
Program Support Center  
5600 Fishers Lane, Room 16 - 65  
Rockville, MD 20857

Date: 5/21/2012

PSC Contact:

Project: Conversion Services

Agency: PSC - Div of Support Services

PSC Contact Phone: 301-594-0553

Email:

Prepared By

Name:

Phone:



Item	Description	Quantity	Unit Price	Total Price
1	Analyze data from client supplied hard drive. Convert files from various formats to pdf for printing	1	\$4,000.00	\$4,000.00
			<b>SUBTOTAL</b>	<b>\$ 4,000.00</b>

<b>Total Order</b>	<b>\$ 4,000.00</b>
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Notes:



5/23/2012  
Date

- Payment terms are net 30 days.



## United States Government Printing Office

### USING THE GPO BAR CODE COVER SHEET

Using the GPO barcode cover sheet and faxing your invoice to GPO is the fastest and safest method of getting paid. Your voucher goes directly into the electronic database of vouchers and is scheduled for payment. Your voucher will never be lost in the mail again!

In order for the system to process your faxed invoices, it is imperative that each invoice be in the following order:

1. **Bar Code Cover Sheet**
2. **Invoice**
3. **Print Order/Purchase Order**
4. **Proof of Delivery**

*512*  
Fax to (202) 512-1851

If the invoice is not in this exact order, it will decrease the probability of prompt payment. It will have to be handled manually and possibly delay your payment.

Each invoice submitted to GPO for payment must be for only one job and it must contain a copy of the purchase order/print order and proof of delivery. If a delivery receipt contains proof of delivery for more than one job, the receipt must be duplicated and a copy submitted with each invoice.

Bar code cover sheets can be created from two sources:

1) On the Internet go to:

<http://winapps.access.gpo.gov/fms/vouchers/barcode/> and complete the bar code cover sheet according to the instructions below. The web page works with any personal computer supporting Adobe Acrobat.

2) Download the bar code cover sheet program zip file (requires Winzip) from the web site: [http://winapps.access.gpo.gov/fms/vouchers/barcode/software/GPOCS\\_25A.ZIP](http://winapps.access.gpo.gov/fms/vouchers/barcode/software/GPOCS_25A.ZIP) and save it to a directory on your local or network hard drive (Example: C:\Program Files).

Once downloaded to your PC, unzip the files, using **WINZIP**, to a local or network hard drive. Run the setup.exe file that was extracted. After program installation, click on the **START - PROGRAMS - GPO Barcode Coversheet - GPO Barcode Coversheet**. This program requires a personal computer running Windows 98, NT, 2000 or XP. Once installed the stand-alone program creates the cover sheet faster than the web page.

After you create the bar code cover sheet and put it together with your invoice in the proper order, fax it to **(202) 512-1851**. You can fax several invoices together as long as each invoice is put in the proper order with the bar code cover sheet separating each invoice.

### COVER SHEET INSTRUCTIONS

The following instructions are to assist you in completing the cover sheet that is required for each printing and binding invoice submitted to the Government Printing Office (GPO) for payment.

**United States Government Printing Office**

Vendor:

Invoice Number:

Purchase Order:

Jacket Number:

Print Order Number:

Terms:  %

Days:

Copyright (c) 2003 - Results Engineering, Inc.

1) The form has the following fields:

**Vendor Name:** (Enter your company name in capital letters - mandatory field)

**Invoice Number:** (Enter your invoice number - mandatory field)

**Purchase Order Number:** (Enter the five-digit GPO purchase order number - mandatory field)

**Jacket Number:** (Enter the six-digit GPO jacket number - mandatory field)

**Print Order Number:** (Enter the five-digit print order number or 00000 if there is none - mandatory field)

**Terms:** (Enter the prompt payment discount terms if one is offered or 00.000 if none. Example: 2% would be entered as 02.000)

**Days:** *(Enter the number of days for the prompt payment discount or leave blank if none)*

**Printing Invoice Type:** *(Leave this alone, it should read 'Printing Invoice')*

**2)** Once you have entered the data on the form, click on the **submit** button.

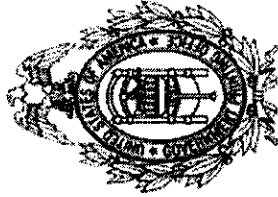
**3)** In the stand-alone program this will create a bar code cover sheet, in a separate window, that you can print by clicking on the **print** button directly above the form. After printing the cover sheet you can close the window. On the web page the cover sheet is created in the same browser window.

**4)** In the stand-alone program, to go back to the entry form, select the entry form window. On the web page, click on the 'Back' button in your browser.

**5)** In the stand-alone program to create additional bar code cover sheets, change the fields on the form and click on the submit button at the bottom of the form. This will create a new cover sheet for each invoice entered. If you want to clear the form and start over, click on the **Clear** button at the bottom and begin entering new data. On the web page click on the 'Back' button in your browser.

**6)** To exit the form in the stand-alone program click on the X at the top right hand corner of the window.

**7)** If you need help, you can call Virgie (Cookie) Simpson, Customer Service Controller's office, GPO at **(202) 512-0864**.



# United States Government Printing Office

## Government Printing Office Payment Processing Cover Sheet for Printing Invoices

**Instructions:** Please complete the following payment processing cover sheet when submitting invoices for payment. [Click here for detailed instructions](#)  
All fields are required except for Print Order Number and Discount Terms and Days. If there is a Print Order Number please delete the zeros and enter the number. If special Discount Terms and Days are offered please enter them.

**"Terms" field format** - Terms must be entered in "00.000" format. (example: 2% should be "02.000")

### Payment Summary Information

Vendor Name   
Invoice Number   
Purchase Order Number   
Jacket Number   
Print Order Number

Terms  00.000  %  Days

Printing Invoice Type  Printing Invoice