

Gasper, John

From: [REDACTED]
Sent: Wednesday, December 07, 2011 12:40 PM
To: Gasper, John
Subject: RE: FDA Asbestos in Talc Lab Survey - Question on LODs and LOQs

Hi John

I'm doing well. I hope you are as well.

These are the descriptions of LOQ and LOD from the spreadsheets I sent you.

Limit of Detection TEM: The weight of the smallest countable chrysotile asbestos fiber is 1.60×10^{-15} grams. The detection limit is based on the effective filter area (EFA), the dilution factor (DF), the mass of asbestos (M), the area analyzed (AA), and the initial sample mass (IM). The equation used is $(EFA * DF * M) / (AA * IM)$. The result is multiplied by 100 to convert it to a percentage.

Limit of Quantification TEM: The asbestos percent determination by TEM is a calibrated visual estimate. A proficiency qualified analyst can estimate asbestos to 0.5%. To determine the quantification limit the equation $((0.5\% * \text{sample weight after preparation}) / \text{initial sample weight})$ is used.

I can't really think of a better way to explain the difference. It boils down to the limit of quantification is based what the percentage would be if a single tiny fiber was all that was found in the sample. The limit of detection is based on what an experienced analyst can reliably estimate, approximately 0.5%. So when you apply the weight of one tiny fiber to the LOD equation above it results in a number much smaller than applying the 0.5% to the LOQ equation.

If it helps, I can talk to the person directly.

Thanks
[REDACTED]
[REDACTED]

Laboratory Director
AMA Analytical Services, Inc.
4475 Forbes Blvd
Lanham, MD 20732
1-800-346-0961

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Tuesday, December 06, 2011 1:44 PM
To: [REDACTED]
Subject: FDA Asbestos in Talc Lab Survey - Question on LODs and LOQs

Andreas,

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Wednesday, December 07, 2011 12:40 PM
To: Gasper, John
Subject: RE: FDA Asbestos in Talc Lab Survey - Question on LODs and LOQs

Hi John

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Limit of Quantification TEM: The asbestos percent determination by TEM is a calibrated visual estimate. A proficiency qualified analyst can estimate asbestos to 0.5%. To determine the quantification limit the equation $((0.5\% * \text{sample weight after preparation}) / \text{initial sample weight})$ is used.

I can't really think of a better way to explain the difference. It boils down to the limit of quantification is based on what the percentage would be if a single tiny fiber was all that was found in the sample. The limit of detection is based on what an experienced analyst can reliably estimate, approximately 0.5%. So when you apply the weight of one tiny fiber to the LOD equation above it results in a number much smaller than applying the 0.5% to the LOQ equation.

If it helps, I can talk to the person directly.

Thanks

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Sent: Tuesday, December 06, 2011 1:44 PM
To: [REDACTED]
Subject: FDA Asbestos in Talc Lab Survey - Question on LODs and LOQs

Andreas,

9/18/2012

How are you? I trust all is well. I've been asked a question on why the TEM limit of quantitation is so much higher than the limit of detection. I know in general that the LOQ is always higher than the LOD because detecting a signal isn't the same as measuring it accurately. However, I was wondering if you could provide me with a more detailed explanation as it applies to TEM and analysis of asbestos in talc. Thank you.

Regards,
John Gasper
OCAC
FDA

Gasper, John

From: [REDACTED]
Sent: Thursday, March 31, 2011 9:09 AM
To: Gasper, John
Subject: Final Invoice for Talc in Asbestos Project
Attachments: AMA Final Invoice for FDA.pdf



AMA Final
Invoice for FDA.pdf

John,

Attached is the final invoice for the talc project.
Thanks a bunch for your help.

[REDACTED]
AMA Analytical Services, Inc.
1331 Ashton Road, Box 646
Hanover, MD 21076
410-684-3327 Office
410-684-3384 Fax
410-227-3220 Mobile
www.amaconsulting.com <<http://www.amaconsulting.com>>

Gasper, John

From: [REDACTED]
Sent: Monday, January 24, 2011 3:26 PM
To: Gasper, John
Subject: Agenda for Friday's Meeting

Hi John,

The following are the topics that we plan on covering:

- 1) Overview of the procedure
- 2) Problems encountered and solutions
- 3) Types of samples
- 4) Criteria used for ID of asbestos
- 5) Review of Analysis
- 6) Results
- 7) Conclusions

Andreas will have a small powerpoint presentation, which he'll email to you in advance of the meeting.

Please let me know if you need anything else.

Thanks!!

PLEASE NOTE NEW CELL PHONE NUMBER BELOW

AMA - Focused on Results!!



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(301) 459-2643 Fax
(410) 491-2738 Mobile

[REDACTED]
www.amalab.com

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Wednesday, January 12, 2011 10:11 AM
To: Gasper, John
Subject: RE: Final Meeting - Talc Project

Forgot about the list of attendees...

[REDACTED] Lab Director & VP
[REDACTED] Director of Client Services
[REDACTED]

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(410) 491-2738 Mobile

[REDACTED]
www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Wednesday, January 12, 2011 9:24 AM
To: [REDACTED]
Subject: RE: Final Meeting - Talc Project

[REDACTED]

I checked with my bosses and it's ok to have your CEO accompany you to this meeting. In addition, would you please send me a list of attendees with their titles, and a proposed agenda. Lastly, if you are going to do a PowerPoint presentation or something similar, please send that information via email beforehand so that I can load it on to a computer for you. Our security rules don't allow for outside thumb drives to be used. We require these things for all meetings. Thank you and we look forward to your presentation.

Regards,
John

From: [REDACTED]
Sent: Friday, January 07, 2011 3:53 PM
To: Gasper, John
Cc: [REDACTED]
Subject: RE: Final Meeting - Talc Project

9/18/2012

John,

We'll get back to you on Monday with a final date.

In the meantime, I put all of the reports on a disc. They're huge files that won't email well. I send that disc via USPS for your receipt next week.

As a side note, our CEO [REDACTED] may accompany us on this last meeting. Would that be a problem?

Thanks!!

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[REDACTED]
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From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Friday, January 07, 2011 3:11 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Final Meeting - Talc Project

[REDACTED]
The best possible dates and times for you to come and present your work are as follows:

Mon 1/24 9-11 am
Tues 1/25 afternoon
Wed 1/26 morning, or 3-4 pm
Thur 1/27 1-2 pm
Fri 1/28 1:30 - on

Please send me your preference and I'll work on the necessary arrangements here.

Also, please send me a copy of the final report beforehand so I can make sure all the revisions we asked for in the 12/14/10 email were completed.

We look forward to hearing your presentation. Thank you.

Regards,
John Gasper
OCAC
301-436-1133

9/18/2012

From: [REDACTED] ⁶⁶
Sent: Monday, January 03, 2011 4:50 PM
To: Gasper, John
Cc: [REDACTED] ⁶⁶
Subject: Final Meeting - Talc Project

Hi John,

I hope that you enjoyed the Holidays.

I have burned all of the reports, data packages, and spreadsheets to a single disc, which I will bring with me to our final meeting. We will also bring all of the samples to that meeting.

We have all TEM grids for the project and will turn them over to the FDA. But all sample slides were destroyed shortly after QC procedures were completed.

[REDACTED] ⁶⁶ and I would like to schedule our final meeting with you before the end of the month. Please provide us with a list of likely dates so we can get it scheduled.

I will not be in the office tomorrow, but [REDACTED] ⁶⁶ should be here all day. Also, you will be able to get me on my cell at almost any point tomorrow.

Thanks!!

PLEASE NOTE NEW CELL PHONE NUMBER BELOW

AMA - Focused on Results!!



[REDACTED] ⁶⁶
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AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
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(410) 491-2738 Mobile

[REDACTED] ⁶⁶
www.amalab.com

Gasper, John

From: [REDACTED]
Sent: Wednesday, January 12, 2011 10:09 AM
To: Gasper, John
Subject: RE: Final Meeting - Talc Project

Hi John,

That sounds great.

Please put us on your calendar for Friday 1/28 starting at 1:30. I can't imagine that we'll be there for more than 2hrs. I will pass the word along to [REDACTED]

Thanks!!

PLEASE NOTE NEW CELL PHONE NUMBER BELOW

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[REDACTED]

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John

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9/18/2012

Cc: [REDACTED]
Subject: RE: Final Meeting - Talc Project

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Sent: Friday, January 07, 2011 3:11 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Final Meeting - Talc Project

Hi [REDACTED]

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Mon 1/24 9-11 am
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Thur 1/27 1-2 pm
Fri 1/28 1:30 - on

Please send me your preference and I'll work on the necessary arrangements here.

Also, please send me a copy of the final report beforehand so I can make sure all the revisions we asked for in the 12/14/10 email were completed.

We look forward to hearing your presentation. Thank you.

Regards,

9/18/2012

John Gasper
OCAC
301-436-1133

From: [REDACTED]
Sent: Monday, January 03, 2011 4:50 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Final Meeting - Talc Project

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[REDACTED] and I would like to schedule our final meeting with you before the end of the month. Please provide us with a list of likely dates so we can get it scheduled.

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9/18/2012

Gasper, John

From: [REDACTED]
Sent: Tuesday, November 23, 2010 4:38 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Re: FDA Asbestos in Talc Study - Final Report
Attachments: Optical Properties Chart.pdf

Hi John

The ELAP methods don't specify criteria and characteristics for the determination of asbestos. Their methods defers to the EPA. I've attached the "optical properties of asbestos fibers" chart from the EPA PLM test method. That method refers to a >10:1 aspect ratio. Other methods such as AHERA and NIOSH 7402 have 5:1 and 3:1 aspect ratios. For our analysis it almost doesn't matter as we saw no fibers at all that main any of the criteria.

When we have our meeting I will bring a DVD with all of the photomicrographs. The files are to large to email.

For 199717 the data package is incorrect. The statement that "...SAED, showed that all particles examined had a hexagonal pattern..." will be corrected for this Chain of Custody. It was an error. We had copied sections of previous data packages.

We have blind spikes for three of the five chain of custodies. That data is included in each data package.

COC 197674 sample RB10 085 was spiked with 5% chrysotile. The analyst estimated 8%.

COC 199229 sample RB10 121 was spiked with 10% chrysotile. The analyst estimated 15%.

COC 199717 sample RB10 146 was spiked with 5% chrysotile. The analyst estimated 7%.

Regarding the variation in acid soluble results for the samples you pointed out there could be a few different explanations ranging from sample homogeneity to laboratory error. I will run these samples through gravimetry again.

For the format issues we will make the changes to the columns and make it clearer that the each unit was analyzed in triplicate.

After we get these items corrected we'll get with you to set up the meeting with you.

Have a great Thanksgiving

[REDACTED]

----- Original Message -----
From: Gasper, John
To: [REDACTED]

9/18/2012

Sent: Wednesday, November 10, 2010 3:11 PM
Subject: FDA Asbestos in Talc Study - Final Report

We've reviewed the final report and we have some things we'd like to be addressed before acceptance.

The following are scientific questions we would like to be addressed in the final report before acceptance:

- What were the selection criteria and/or specific fiber characteristics used to determine whether or not something qualifies as asbestos? (i.e. what fiber length and aspect ratio were used). This is important because labs routinely argue over findings due to the definition selected for the determination. (are they in the ELAP methods?)
- We would like copies of any photomicrographs that exist for the samples. This is because they are the actual evidence which supports the conclusion of no asbestos being detected. With these in hand, we will have a much more compelling argument in support of the findings.
- We need some clarification and possible further expansion of the "Discussion and Interpretation of Analytical Findings" for Data Package 199717 found on page 36. This statement reads: *"No asbestos fibers or structures were detected by PLM or TEM. In addition, no fibrous components were observed. Particles from each sample were examined. The selected area diffraction, SAED, showed that all particles examined had a hexagonal pattern. This is consistent with talc. The electron dispersive x-ray analysis, EDXA, showed that each particle examined consisted of silica and magnesium."* We're concerned about this statement because it suggests that the products analyzed contained only talc. (see ... *all particles examined had a hexagonal pattern. This is consistent with talc.*) Considering that samples were labeled to contain mica and silica, which are not talc, we would like this statement rewritten with this in mind.
- Were any blinded positive controls analyzed? These would show that asbestos would have been detected had it been present in any samples.
- Are there any SAED or EDXRA data for the product sample analyses?
- Do you have any explanation for what appears to be significant variation in the results for % acid soluble? We are interested in this as the talc raw material specification sheets supplied by the manufacturer suggest a higher purity than the % acid soluble data show. (See Johnson & Johnson Baby Powder product analyses 1049802-1049804 and talc raw material 1043257-1043259).

The following are format issues we would like to be addressed in the final report before acceptance:

- Table header "Cosmetics and Colors" should be changed to "Office of Cosmetics and Colors"
- Column heading "Client Sample #" should be changed to "Product Identity"
- By labeling the triplicate analyses of each sample as "A, B, C" under "Client Sample #", it's not clear if this means it is the same unit analyzed three times or if it means three separate units. Please reword to clarify each sample was analyzed in triplicate. For example, an asterisk and a footnote that explains this.
- Add the two previous reports to the cd that were not included but were sent in hard copy.

On a related note, after this is finished, I spoke with the group and we like [REDACTED] idea of coming here to give a talk on the report. We anticipate that a good group will look forward to his presentation.

If you have any questions, please do not hesitate to contact me. Thank you.

Regards,
John Gasper
Office of Cosmetics and Colors
CFSAN
301-436-1133

Amosite (asbestiform grunerite)	Straight to curved, rigid fibers. Aspect ratio typically >10:1. Colorless to brown, nonpleochroic or weakly so. ⁴ Opaque inclusions may be present	1.657-1.663 1.699-1.717 1.663-1.686 1.696-1.729 1.663-1.686 1.696-1.729 1.676-1.683 1.697-1.704	0.021-0.054	Usually parallel	+ (length slow)
Crocidolite (asbestiform riebeckite)	Straight to curved, rigid fibers. Aspect ratio typically > 10:1. Thick fibers and bundles common, blue to dark-blue in color. Pleochroic.	1.693 1.697 1.654-1.701 1.668-1.717 1.680-1.698 1.685-1.706	0.003-0.022	Usually parallel	(length fast)
Anthophyllite- asbestos	Straight to curved fibers and bundles. Aspect ratio typically > 10:1. Anthophyllite cleavage fragments may be present with aspect ratios <10:1. Colorless to light brown.	1.598-1.652 1.623-1.676 1.596-1.694 1.615-1.722 1.598-1.674 1.615-1.697 1.6148 ⁷ 1.6362 ⁷	0.013-0.028	Parallel	+ (length slow)
Tremolite- Actinolite- asbestos	Straight to curved fibers and bundles. Aspect ratio typically > 10:1. Cleavage fragments may be present with aspect ratios <10:1. Colorless to pale green	Tremolite 1.600-1.628 1.625-1.655 1.604-1.612 1.627-1.635 1.599-1.612 1.625-1.637 1.6063 ⁷ 1.6343 ⁷ Actinolite 1.600-1.628 1.625-1.655 1.612-1.668 1.635-1.688 1.613-1.628 1.638-1.655 1.6126 ⁷ 1.6393 ⁷	0.017-0.028 0.017-0.028	Parallel and oblique (up to 21°); Composite fibers show parallel extinction.	+ (length slow)

¹Colors cited are seen by observation with plane polarized light.

²l to fiber length, except $\perp$ to fiber length for crocidolite only.

³From references 2, 11, 12, and 18, respectively. Refractive indices for n_z at 589.3nm.

⁴Maximum and minimum values from references 2, 11, 12, and 18 given.

⁵Fibers subjected to heating may be brownish. (references 13, 14, and 15)

⁷ ± 0.0007

⁸Fibers subjected to heating may be dark brown and pleochroic. (references 13, 14, and 15)

Gasper, John

From: [REDACTED]
Sent: Friday, November 12, 2010 1:59 PM
To: Gasper, John; [REDACTED]
Subject: Re: FDA Asbestos in Talc Study - Final Report

Hi John

I just wanted to let you know I'll work on the answers and get back to you early next week. Also [REDACTED] is back next week and we can all coordinate our schedules to figure out when would be the best time for a meeting.

Have a good weekend
[REDACTED]

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

From: Gasper, John
To: [REDACTED]
Sent: Wednesday, November 10, 2010 3:11 PM
Subject: FDA Asbestos in Talc Study - Final Report

[REDACTED]

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9/18/2012

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If you have any questions, please do not hesitate to contact me. Thank you.

Regards,
John Gasper
Office of Cosmetics and Colors
CFSAN
301-436-1133

Gasper, John

From: [REDACTED]

Sent: Thursday, October 14, 2010 4:09 PM

To: Gasper, John

Subject: elap methods

<http://www.wadsworth.org/labcert/elapcert/certmanual/index.html>

AMA - Focused on Results!!



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(410) 562-9699 Mobile

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Gasper, John

From: [REDACTED]
Sent: Wednesday, September 29, 2010 7:21 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Administrative Synopsis from AMA
Attachments: Administrative Synopsis - Asbestiform Analysis of Cosmetic Talc.pdf

Hi John,

My many apologies for the delay in getting this last little report to you. The technical difficulties we were experiencing earlier this week prevented me from being able to send this out to you earlier.

Please review the attached. It is a summary of the success (or lack thereof) we had in obtaining bulk raw material and cosmetic products. I've also included a brief discussion of the format of our reports and how they were delivered. Please let me know if there is anything else of an administrative nature you'd like included on this synopsis. If there is additional technical information, data, or explanations, please contact [REDACTED]

Otherwise, between this PDF file, the reports we sent on 7/30/2010, and the spreadsheet [REDACTED] compiled on 9/24/2010, we consider the project complete.

Please do not hesitate to contact me with any additional questions or concerns that you may have.

It was a pleasure working with you and your team on this project. We appreciate the opportunity to demonstrate the value of our services to the FDA and hope that we will be afforded a similar opportunity in the future.

Thanks!!

AMA - Focused on Results!!



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[REDACTED]
www.amalab.com

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Friday, September 24, 2010 7:23 PM
To: Gasper, John
Subject: Re: Data Package for FDA - Analytical Sensitivity
Attachments: LOD and LOQ 199717.xls; LOD and LOQ 197155.xls; LOD and LOQ 197229.xls; LOD and LOQ 197674.xls; LOD and LOQ 199229.xls

Hi John

All of the new spreadsheets are attached.

Thanks
[REDACTED]

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

From: Gasper, John
To: [REDACTED]
Sent: Friday, September 24, 2010 3:05 PM
Subject: RE: Data Package for FDA - Analytical Sensitivity

[REDACTED]

One last comment. In the footnote "Limit of Quantification TEM" where it says "A calibrated analyst ...", could you change this to read something like "A proficiency qualified analyst ...".

We're not sure that "calibrated" is the right word here and so other readers would be confused as well. Thank you.

Regards,
John Gasper
Office of Cosmetics and Colors
CFSAN
FDA
301-436-1133

From: [REDACTED]
Sent: Thursday, September 23, 2010 12:53 PM
To: [REDACTED] Gasper, John
Subject: Re: Data Package for FDA - Analytical Sensitivity

Hi John

Here's what I've worked up. I changed the headings on the spreadsheet and added the actual limit of detection. I've also added footnotes to explain the LOQ and LOD plus TEM vs PLM. If this spreadsheet is ok with you, I'll do up the rest of samples and send them to you tomorrow.

Thanks
[REDACTED]

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

From: Gasper, John

9/18/2012

To: [REDACTED]
Cc: [REDACTED]
Sent: Monday, September 13, 2010 2:48 PM
Subject: RE: Data Package for FDA - Analytical Sensitivity

[REDACTED]

This note is a follow-up to your email of August 19, 2010 in which you explain that the column heading term "Analytical Sensitivity" in the tabulated data submitted to us should really refer to "Limit of Quantitation." We concur.

Pursuant to the tabulated data, the analyses involved two techniques; specifically, polarized light microscopy (PLM) and transmission electron microscopy (TEM). A novice looking at these tables might infer that these two techniques are equivalent. Can you present the data and other relevant information in such a fashion that the superior performance characteristics of TEM are captured relative to the PLM technique? We are open to ideas on how you might accomplish this. Is the limit of quantitation the same for both techniques?

One way to capture this issue is through the use of a footnote to the table, but maybe you can suggest something more clever and easier to "visualize." Overall, we need these issues captured and explained in the report to ensure that whoever reads it can easily understand it.

We also noticed in one of the data tables, provided on 8/10/10, an incorrect title. In the table, after "job location", it states "Samples Provided by Rio Tinto Minerals/Luzenac Ame." However, the reported findings refer to cosmetic products that were purchased and tested. They are definitely not samples provided by Rio Tinto. Please check these spreadsheets and correct where necessary.

If you need further clarification on any of the issues discussed here, feel free to contact me directly. Thank you.

Regards,
John Gasper
OCAC
FDA
301-436-1133

Gasper, John

From: [REDACTED]
Sent: Thursday, September 23, 2010 12:53 PM
To: [REDACTED] Gasper, John
Subject: Re: Data Package for FDA - Analytical Sensitivity
Attachments: LOD and LOQ 197155.xls

Hi John

Here's what I've worked up. I changed the headings on the spreadsheet and added the actual limit of detection. I've also added footnotes to explain the LOQ and LOD plus TEM vs PLM. If this spreadsheet is ok with you, I'll do up the rest of samples and send them to you tomorrow.

Thanks

[REDACTED]

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

From: Gasper, John
To: [REDACTED]
Cc: [REDACTED]
Sent: Monday, September 13, 2010 2:48 PM
Subject: RE: Data Package for FDA - Analytical Sensitivity

[REDACTED]

This note is a follow-up to your email of August 19, 2010 in which you explain that the column heading term "Analytical Sensitivity" in the tabulated data submitted to us should really refer to "Limit of Quantitation." We concur.

Pursuant to the tabulated data, the analyses involved two techniques; specifically, polarized light microscopy (PLM) and transmission electron microscopy (TEM). A novice looking at these tables might infer that these two techniques are equivalent. Can you present the data and other relevant information in such a fashion that the superior performance characteristics of TEM are captured relative to the PLM technique? We are open to ideas on how you might accomplish this. Is the limit of quantitation the same for both techniques?

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If you need further clarification on any of the issues discussed here, feel free to contact me directly. Thank you.

Regards,
John Gasper
OCAC
FDA
301-436-1133

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Wednesday, September 22, 2010 10:25 AM
To: Gasper, John
Subject: Re: Data Package for FDA - Analytical Sensitivity

Hi John

I've been out on medical leave but I'm back now. I will have something to you on this by the end of the week.

Thanks
[REDACTED]

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

From: Gasper, John
To: [REDACTED]
Cc: [REDACTED]
Sent: Monday, September 13, 2010 2:48 PM
Subject: RE: Data Package for FDA - Analytical Sensitivity

[REDACTED]

This note is a follow-up to your email of August 19, 2010 in which you explain that the column heading term "Analytical Sensitivity" in the tabulated data submitted to us should really refer to "Limit of Quantitation." We concur.

Pursuant to the tabulated data, the analyses involved two techniques; specifically, polarized light microscopy (PLM) and transmission electron microscopy (TEM). A novice looking at these tables might infer that these two techniques are equivalent. Can you present the data and other relevant information in such a fashion that the superior performance characteristics of TEM are captured relative to the PLM technique? We are open to ideas on how you might accomplish this. Is the limit of quantitation the same for both techniques?

One way to capture this issue is through the use of a footnote to the table, but maybe you can suggest something more clever and easier to "visualize." Overall, we need these issues captured and explained in the report to ensure that whoever reads it can easily understand it.

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If you need further clarification on any of the issues discussed here, feel free to contact me directly. Thank you.

Regards,
John Gasper
OCAC
FDA
301-436-1133

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Thursday, August 19, 2010 9:30 AM
To: [REDACTED] Gasper, John
Subject: Re: Data Package for FDA - Analytical Sensitivity

Hi John

It isn't the limit of detection it's really the limit of quantification. It's based on the analyst's ability to accurately estimate asbestos to the 0.5% level. With TEM we can detect asbestos to much lower levels. If I only saw one or two small fibers during analysis the percentage would be something like 0.0000... (don't how many zeros) percent. So, as I've thought about this more, what I sent you really represents the limit of quantification not the analytical sensitivity. The limit of detection is actually quite low. Here's an example:

A tiny chrysotile fiber with a length of 0.05 microns and a width of 0.025 microns weighs 0.00000063 nanograms. If the initial sample weight was 0.2 grams or 200,000,000 nanograms. You would have to factor in area analyzed, effective filter area, and dilution factor but the percentage one tiny fiber represents is a very small percentage.

The weight of the sample is tracked throughout the preparation process but since the asbestos is visually estimated the result is a semi-quantitative weight percent. The bottom line on all of these samples though is no asbestos has been detected on any of them. If you like though, I can calculate the theoretical limit of detection on each sample.

Thanks

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

From: [REDACTED]
To: [REDACTED]
Sent: Monday, August 16, 2010 5:07 PM
Subject: FW: Data Package for FDA - Analytical Sensitivity

Can you answer this question from John??

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 (410) 562-9699 Mobile

www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Monday, August 16, 2010 4:34 PM
To: [REDACTED]
Subject: Data Package for FDA - Analytical Sensitivity

9/18/2012

Hi [REDACTED]

My group is meeting this Wednesday to discuss the reporting options for analytical sensitivities you sent me on 8/3. I was also looking at the email from [REDACTED] on the same and would like to know exactly what analytical sensitivity, when expressed as a percent, means. For example, one sample has an analytical sensitivity of 0.45%. Does that mean that the limit of detection for that sample is 0.45%? Is this a weight percent? Thank you.

Regards,
John Gasper
OCAC
301-436-1133

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Tuesday, August 10, 2010 4:40 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Analytical Sensitivity
Attachments: Analytical Sensitivity 197674.xls; Analytical Sensitivity 199229.xls; Analytical Sensitivity 199717.xls; Analytical Sensitivity 197155.xls; Analytical Sensitivity 197229.xls

Hi John

Attached are excel spreadsheets for all the projects we have complete so far. The analytical sensitivity is based on 0.5% asbestos in the residue after gravimetric reduction. For example if there was no gravimetric loss in preparation and 100% of the original sample remained, the analytical sensitivity is 0.5%. If 90% was consumed during preparation, leaving 10% residue, the analytical sensitivity is 0.05%.

If you have any questions, please don't hesitate to ask.

Thanks

[REDACTED]
[REDACTED]
Laboratory Director
4475 Forbes Blvd.
Lanham, Maryland 20706
1-800-346-0961

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Tuesday, August 03, 2010 2:01 PM
To: Gasper, John
Subject: Data Packages from AMA

Hi John,

I hope all is well in your world. We are certainly very busy here in the laboratory, but then again, 'tis the season.

At any rate, I wanted to let you know that I have final data packages for COCs 199229 & 199712. I tried something a little new when I made the electronic versions of these files – I bookmarked the pages to make it easier to navigate around the document and get to exactly what you need. The data package for 199712 is HUGE – it's over half a ream of paper, so the file itself is gigantic. As a result, I've burned the PDF files for these two data packages to a disc, which I'm sending your way via FedEx or UPS – you should have it along with the hard copy reports tomorrow.

I also wanted to take a minute to discuss analytical sensitivities, which are going to vary from sample to sample depending on the amount of sample that was filtered for each sample. Andreas and I were tossing around ideas on how to present this data to you. We talked about revising the report format, but that would require us to spend a lot of timing re-programming the database. So, we came up with the following, but would like for you to pick what would work best for your purposes:

- 1) We will hand enter the AS for each sample into the comments section of the report. This would also mean that we would need to issue a revised certificate of analysis for each report.
- 2) We could include the data in the sample table of each case narrative. This would also mean that we would need to issue revised a revised case narrative for each report.
 - a. Though, as I'm typing this out, we would probably have to revise the case narratives to include a brief discussion on how we calculate AS (hmmm... I'll have to discuss that with [REDACTED]).
- 3) We could include that data in spreadsheet format at the end of the project with a single spreadsheet for all samples submitted.

Now for some contract/billing issues, which affect the number of additional samples to be analyzed...

- 1) To date we have billed a total of 28,964.71 to the PO.
 - a. 27,450 out of the 40,000 to line item 1.
 - i. 61 sample, 183 analyses
 - ii. Line item 1 – “total cost to process 78 talc-containing products in triplicate to determine asbestiform materials – about 234 analyses)
 - b. 1,514.71 out of 58,748 to line item 2-IDIQ.
 - i. Labor and materials time
 1. Is it possible that I should be counting this amount towards line item 1?
 - ii. Line item 2 – “at the discretion of the contracting officer, the government may use the IDIQ line item for the contractor to purchase cosmetic grade talc and talc products for analysis beyond the 78 samples and to be reimbursed for costs incurred in the performance of the task orders to include labor and materials or combination thereof.
- 2) If the above totals are correct, then we have a total of 17 samples remaining on the contract under the first line item.
- 3) If the government so chooses, there is also enough money left on the PO for analyze an additional 120-125 samples (360-375 analyses).

9/18/2012

- a. Have you heard from Jose Bumbray about modifying the PO so that line item allows for more samples or about tapping into the money in the 2nd line item?
- 4) The following is a brief summary on where we stand in obtaining material from the other bulk raw suppliers:
 - a. Chrystal
 - i. As of March they confirmed that they received the request, but we have not yet seen the samples.
 - ii. I will follow-up with them this week. I think I'm going to start all over from scratch and just place a new order.
 - b. Creations Colours
 - i. I have received your draft email request to send to them and thought that I had done so at the beginning of June, but can find no record of the email.
 - ii. I will email them this week.
 - c. Specialty Minerals
 - i. We have made initial contact with them.
 - ii. I will do so this week.
 - d. Golcha
 - i. I have send 3 emails via their website, but have not yet received a response from them.
 - ii. I will try and contact them via phone this week, but that may be difficult given the time difference.

Give me a call with any questions or concerns that you may have.

Thanks!!

AMA - Focused on Results!!



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Gasper, John

From: Results from AMA Analytical Services [results@amalab.com]
Sent: Friday, July 02, 2010 9:31 AM
To: Gasper, John
Subject: FW: TEM bulk result for COC#199717
Attachments: 199717 FDA.pdf

John,

Attached is the preliminary report for the analysis of all the make-up products on your list.

We plan on having a finalized report for on both these analyses and the sample material from Rio Tinto by mid-July.

I hope you have a wonderful holiday and I look forward to speaking with you in more detail next week.

Thanks!!

PS – My apologies for the delay in getting these results to you... my guys had initially sent the report to an incorrect email address as you can see below.

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www.amalab.com

From: Results from AMA Analytical Services [mailto:results@amalab.com]
Sent: Wednesday, June 30, 2010 11:33 PM
To: john.gaspen@fda.hhs.gov
Subject: TEM bulk result for COC#199717

AMA - Focused on Results!!

DO NOT REPLY TO THIS EMAIL, AS THIS ACCOUNT IS NOT REGULARLY MONITORED FOR INCOMING MAIL.

9/18/2012

This e-mail message and attachments, if any, are intended solely for the use of the addressee thereof. In addition, this message may contain information that is confidential, privileged and exempt from disclosure under applicable law. If you are not the intended recipient of this message, you are prohibited from reading, disclosing, reproducing, distributing, disseminating, or otherwise using this transmission. Delivery of this message to any person other than the intended recipient is not intended to waive any right or privilege. If you have received this message in error, please promptly notify the sender and immediately destroy this transmission.

The final certificate will be mailed once quality control has been performed for this chain of custody.

Gasper, John

From: Gasper, John
Sent: Wednesday, June 02, 2010 11:09 AM
To: [REDACTED]
Subject: RE: Product List
Attachments: Draft AMA Email to Creations Couleurs 052710.doc

[REDACTED]

We approve the list of products you purchased and would like you to proceed with their analysis. I found the detailed summary of information most helpful.

In addition, please find attached a draft email for you to use to send to Creations Couleurs to obtain raw cosmetic grade talc. Please use that language in your email to them. Thank you.

Regards,

John Gasper
OCAC

From: [REDACTED]
Sent: Friday, May 28, 2010 3:08 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Product List

John,

I was able to find and purchase every item on the list that you provided us.

I have attached a detailed summary of the products and we will await your final approval before analysis begins.

Have GREAT Holiday Weekend!!

AMA - Focused on Results!!



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[REDACTED]
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9/18/2012

Draft Email for AMA to Send to Creations Couleurs

Dear Madam or Sir:

We respectfully request that you provide us with a sample of Talcpoly WL 10 PUR and a sample of Talcpoly WL 12 PUR. Please note that your Mr. Alain Saintrond has agreed to honor this request based upon a conversation he had with Mr. John Gasper on May 26, 2010. Mr. Gasper is from the Office of Cosmetics and Colors in the U.S. Food and Drug Administration.

We need only approximately 4 oz. samples of each product. Please ship the materials to:

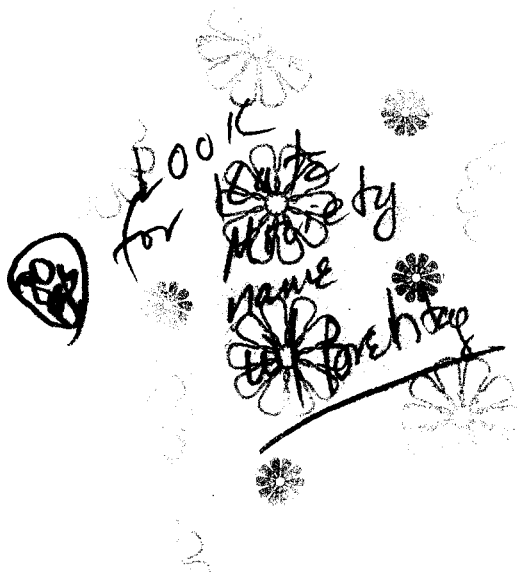
AMA Analytical Services
Attn: [REDACTED]
4475 Forbes Blvd.
Lanham, MD 20706, USA

We appreciate your cooperation in this request and look forward to receiving these samples.

Sincerely,

[REDACTED]
AMA Analytical Services
(Phone and Address Info)

C:\Documents and Settings\john.gasper\My Documents\Talc Lab Survey\Talc Study Proposal\AMA Analytical\Draft AMA Email to Creations Couleurs 052710.doc



Gasper, John

From: [REDACTED]
Sent: Monday, May 10, 2010 10:24 AM
To: Gasper, John
Subject: Electronic Results from COC 197674
Attachments: 197674 FDA.pdf

Hi John,

Here are the analytical results and the data package for the most recent set of samples.

Please let me know if you need anything else.

Thanks!!

Gasper, John

From: [REDACTED]
Sent: Wednesday, April 21, 2010 11:59 AM
To: Gasper, John
Subject: RE: FDA - Talc

Hi John,

Whittaker, Clark & Daniels (Brenntag): Samples Received
Presperse: Samples Received
Ultra Chemical: Will not send samples without additional information
Chrystal: Placed order on 2/16/10, but have not yet received samples. Will re-order.
LCW-USA: Samples Received
Creations Colours: Will only send samples if "our client places order with them directly."
Rio Tinto: Will not send samples without additional information (You have a list of the questions they would like answered before we proceed)
Specialty Minerals: Still need to contact
Golcha: Still need to contact

Thanks!!

AMA - Focused on Results!!



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From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Wednesday, April 21, 2010 11:51 AM
To: [REDACTED]
Subject: FDA - Talc

[REDACTED]

Can you tell me which companies have submitted samples of raw cosmetic grade talc and which have not? We need this in order to determine how to proceed with those who don't want to so far. Thank you.

Regards,

John Gasper
OCAC
FDA

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Tuesday, April 20, 2010 2:04 PM
To: Gasper, John
Subject: FW: Cosmetic Grade Talc

John,

Here are the questions/concerns from Rio Tinto... I will leave it to the FDA to develop responses for us to deliver to them.

Thanks!!

AMA - Focused on Results!!



[REDACTED]
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[REDACTED]
www.amalab.com

From: [REDACTED] 66
Sent: Tuesday, April 20, 2010 1:44 PM
To: [REDACTED]
Subject: RE: Cosmetic Grade Talc

Hello [REDACTED]

It was a pleasure speaking with you today to understand the scope of your work. We will be happy to provide you with our product samples for your testing. However, we need to understand the scope of your testing program. Specifically:

- What tests do you plan to conduct on our products?
- Who will receive the test results and what do they intend to do with them?
- Will you share test results with Rio Tinto Minerals?
- What information can you share with us about the client or the test program?

[REDACTED] I hope you understand and appreciate our position and our expectation on complete transparency. While we are happy to offer product samples to our potential customers and/or research organizations free of charge, it remains our concern that our products or data may end up in the hands of our competitors.

Thanks you for your understanding and cooperation.

9/18/2012

Best regards,

66

66

Global Talc Regulatory Affairs Manager

Rio Tinto Minerals - Denver

+1 303-713-5227 (O)

+1 303-882-4638 (M)

From:

Sent: Thursday, March 18, 2010 12:57 PM

To: Sharma, Shripal (RTM)

Subject: Cosmetic Grade Talc

Hi 66

I've left you a voice-mail, but figured that an email couldn't hurt.

I'd like to inquire about your catalogue of commercial grade talc and obtaining some sample material.

Please contact me at (301) 459-2640 or simply reply to this email.

Thanks!!

66

Gasper, John

From: [REDACTED]
Sent: Tuesday, April 20, 2010 2:02 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Another Bulk Raw Supplier Bites the Dust

Hi John,

I've just gotten off the phone with Rio Tinto. They too have concerns about sending us sample material, without having a few basic questions answered:

- 1) We are a testing laboratory, not a product supplier or manufacturer, so what are our purposes/intentions.
 - a. I told them that "We have a client who has hired us to perform testing services on their behalf. They have specifically requested that we obtain samples of these materials from your organization for testing purposes."
 - b. I explained the confidentiality clauses of our contract prevent me from releasing any additional information without my client's express permission.
 - c. That was not a satisfactory answer.
- 2) They want to know the context of our testing, among a few other concerns.
- 3) They want to know whether or not they will get a copy of the test results.

I asked them to email a list of question/concerns, which I told them I would send to our client (you). As soon as I receive those questions, I forward them to you and let the FDA work from there.

Thanks!!

AMA - Focused on Results!!



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(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Thursday, April 15, 2010 2:35 PM
To: Gasper, John
Subject: RE: FDA - Talc - Sample Purchase List and Instructions

Hi John,

[REDACTED] is going to be at the ASTM D22.07 sub-committee meeting (in San Antonio, I think) until Wednesday of next week. I think we'd like to come see you guys either Thursday or Friday next week – 4/22 or 4/23.

Talk at ya later... thanks!!

AMA - Focused on Results!!



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[REDACTED]
 www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Wednesday, April 14, 2010 4:19 PM
To: [REDACTED]
Cc: Havery, Donald C; Hansen, Patricia A; Hurley, Fred J
Subject: FDA - Talc - Sample Purchase List and Instructions

[REDACTED]

Please find attached a memo that explains what samples we want you to purchase and analyze. To ensure that you understand what we want, I recommend that we have a short telecon soon to go over it and address any questions or concerns. Please let me know what days and times are convenient so that we may schedule it.

Also, we have one of the samples here. Thus, it may be preferable that either I bring it out to your lab and then we have our short meeting, or you may come here and do the same. Please let me know your preference. Thank you.

Regards,
 John Gasper
 Office of Cosmetics and Colors
 CFSAN

<<Draft Sample Purchase Instructions 041310.doc>>

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Thursday, March 18, 2010 5:54 PM
To: Gasper, John
Subject: RE: FDA - Talc Asbestos Study - Samples

Hi John,

We can analyze as few or as many additional samples as the FDA would like. Our PO for the job is for **64**, which would allow us to analyze a total of ~200 samples in triplicate. So far we've analyzed 20 bulk raw samples, and we expect to receive ~24 additional bulk raw samples. If we're going with the going with the original contract total of 78 samples, then we're left with ~34 samples. If, however, we're working within the terms of what the PO will cover, then we're left with ~156 samples.

I leave it up to the FDA to decide, but it's my opinion that 34 samples will not be sufficient to make up a representative sampling batch of the 15-page catalogue of commercial products that you have.

I look forward to your response.

Thanks!!

AMA - Focused on Results!!



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(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Thursday, March 18, 2010 11:13 AM
To: [REDACTED]
Subject: FDA - Talc Asbestos Study - Samples

Good morning [REDACTED]

I'm in the process of putting together the list of cosmetic samples and there's some information I need from you. How many raw cosmetic talc samples have you obtained? The reason I need this is because the contract calls for 78 total samples so I want to know how many are left to be used for cosmetic products. Thank you.

Regards,
John

John Gasper
Office of Cosmetics and Colors

9/18/2012

CFSAN

Gasper, John

From: [REDACTED]
Sent: Monday, March 15, 2010 4:11 PM
To: Gasper, John
Subject: Results
Attachments: 197674 FDA.pdf

Hi John

Attached are results for received from Brenntag Specialties, Inc. This is the preliminary report. I will send you the full data package by the end of the week.

Thanks

[REDACTED]
[REDACTED]
Laboratory Director
4475 Forbes Blvd.
Lanham, Maryland 20706
1-800-346-0961

9/18/2012

Gasper, John

From: [REDACTED] b6
Sent: Monday, March 15, 2010 2:40 PM
To: Gasper, John
Subject: Re: Sensient Samples with Data Package

Hi John,

Yes, hard copies of both packages will be sent via USPS.

I'll give you a call tomorrow.

Thanks!!

[REDACTED] b6

Sent via BlackBerry by AT&T

From: "Gasper, John" <John.Gasper@fda.hhs.gov>
Date: Fri, 12 Mar 2010 17:23:52 -0500
To: [REDACTED] b6
Subject: RE: Sensient Samples with Data Package

[REDACTED] b6
I got both data packages. Thank you very much. As for the hardcopy packages, are those being sent via regular mail?

I hope you have a most enjoyable weekend.

Regards,
John

From: [REDACTED] b6
Sent: Friday, March 12, 2010 4:26 PM
To: Gasper, John
Subject: Sensient Samples with Data Package

Hi John,

Here are sample results, complete with data package for the sample material that we received from Sensient.

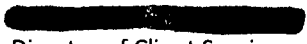
The hardcopy package, along with a copy of the invoice (the original invoice is being sent directly to accounting). This email is coming from my personal yahoo account because it's too big for me to send from AMA account.

Please do not hesitate to contact me with any questions or concerns that you may have.

9/18/2012

Thanks!!
Sincerely,

AMA - Focused on Results!!


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9/18/2012

Gasper, John

From: [REDACTED]
Sent: Friday, March 12, 2010 4:26 PM
To: Gasper, John
Subject: Sensient Samples with Data Package
Attachments: 197229 FDA_with Data Package.pdf

Hi John,

Here are sample results, complete with data package for the sample material that we received from Sensient.

The hardcopy package, along with a copy of the invoice (the original invoice is being sent directly to accounting). This email is coming from my personal yahoo account because it's too big for me to send from AMA account.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thanks!!

Sincerely,

AMA - Focused on Results!!

[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 (410) 562-9699 Mobile
[REDACTED]
www.amalab.com

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Friday, March 12, 2010 4:23 PM
To: Gasper, John
Subject: Presperse Samples w/ Data Package
Attachments: 197155 FDA_with Data Package.pdf

Hi John,

Here are sample results, complete with data package for the sample material that we received from Presperse.

The hardcopy package, along with a copy of the invoice (the original invoice is being sent directly to accounting). This email is coming from my personal yahoo account because it's too big for me to send from AMA account.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thanks!!

Sincerely,

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(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
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9/18/2012

Gasper, John

From: [REDACTED] 66
Sent: Wednesday, March 10, 2010 3:34 PM
To: Gasper, John; [REDACTED] 66
Cc: Hansen, Patricia A
Subject: RE: FDA - Talc and Asbestos Project
Attachments: Analytical Methodology_Response to FOI Request.pdf

Hi John,

Attached, please find our response to the FOI request.

Please give me a call when you have a few minutes so that I can discuss the attachment with you in more detail.

Thanks!!

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[REDACTED]
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Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED] 66
www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Monday, March 08, 2010 3:00 PM
To: [REDACTED] 66
Cc: Hansen, Patricia A
Subject: FDA - Talc and Asbestos Project

[REDACTED] 66

FDA recently received a Freedom of Information (FOI) request that relates to our project with you. What we'd like to know is if you could write up a general overview of the methodology you're employing and if AMA would be comfortable with us releasing that information pursuant to a FOI request. If you have any questions or concerns on this, please do not hesitate to contact me. Thank you.

Regards,
John Gasper
Office of Cosmetics and Colors
CFSAN

9/18/2012



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101143-0

NY ELAP

10920



100470

Analytical Methodology Being Employed on FDA Contract #FDA-09-1061335

We are using a modified version of the NY State ELAP 198.6 / 198.4 methods for the analysis of non-friable organically bound (NOB) materials.

General Preparation

- 1 Weigh the sample container.
- 2 Add approximately 0.5 grams of sample to the container and weigh again.
- 3 Place the sample container into the muffle furnace, set at 480°C, for 12+ hours.
- 4 Remove the sample from the furnace and allow to cool to room temperature.
- 5 Weigh the sample. This is the post ash weight.
- 6 Weigh a Petri dish, a 5µm MCE filter and a 0.4µm PC filter. This is the tare.
- 7 Load a filtration unit with both filters. Make sure the 5µm filter is on the bottom.
- 8 Add hydrochloric acid (HCl) to the sample and allow to sit for 10 minutes.
- 9 Add 30ml of filtered water to the filtration unit.
- 10 Pore the acid treated sample into the filtration unit. Rinse the container several times to make sure the entire sample is filtered.
- 11 Turn on the vacuum pump and rinse the sides of the filtration unit as the solution is drawn through the filter.
- 12 Place both filters in the pre-weighed Petri dish.
- 13 Place the Petri dish, containing the filters, in the drying oven for 30 minutes.
- 14 Take Petri dish out of the oven, allow too cool, and weigh.

PLM Preparation

- 15 In a HEPA filtered hood prepare 4 slides for polarized light microscopy (PLM).

TEM Preparation

- 16 Place the top PC filter in a 100ml jar and add DI water to the 100ml line.
- 17 Place the jar in an ultrasonic bath for 5 minutes.
- 18 Assemble a filtration unit with a 5µm MCE bottom filter and a 0.22µm MCE Top filter.
- 19 Add 50 ml of filtered water to the filtration unit.
- 20 Shake the jar and pipette 0.2ml of the solution into the filtration unit.
- 21 Turn on the vacuum pump and filter the sample.
- 22 Place the 0.22µm MCE Top filter in a Petri dish and place it in the drying oven for 15 minutes.
- 23 Cut and collapse the filter, carbon coat it, cut it, and place it on a TEM grid in dimethylformamide (DMF) solution. Leave the sample on the DMF for 2 hours.
- 24 Remove the sample from the DMF and place it in an acetone bath for 10 minutes.
- 25 Remove the sample from the acetone, allow a few seconds to dry, and place it in a labeled grid box.

PLM Analysis

- 26 Use the EPA 400 point count method for each sample.

Asbestos • Lead • Mold



AMA Analytical Services, Inc.

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NVLAP®

101143-0

NY ELAP

10920



100470

- 27 Record all appropriate optical properties for each fiber type encountered.
- 28 Calculate the percentage of fibrous components found using the recorded weight loss from the preparation process.

TEM Analysis

- 29 Place the sample grid in the holder and insert the holder into the scope.
- 30 20 grid openings at magnifications between 4,800x and 19,000x, Scan.
- 31 If a fiber type is encountered, check the selected area diffraction pattern (SAED) and the chemistry using electron dispersive x-ray analysis (EDXA)
- 32 Visually estimate the percentage of each fiber type.
- 33 Calculate the percentage of fibrous components found using the recorded weight loss from the preparation process.

Quality Control

With each set of samples, a "blank" sample is also prepared. This is a known negative source of talc (Sigma Aldrich Talc Powder, <10µm). This is analyzed as a routine sample. Finding asbestos in this sample would indicate contamination during the preparation process causing any positive result for customer samples to be suspect.

With each set of samples, a reference sample is prepared. The reference sample is Sigma Aldrich Talc Powder, <10µm spiked with a known amount of NIST SRM 1866 Chrysotile. The sample is analyzed as a routine sample prior to analysis of the customer samples. It helps to calibrate the analyst's visual estimate of asbestos in customer samples.

Replicate QC: At least 10% of all the samples are analyzed a second time by another analyst.

Duplicate QC: At least 2% of all samples are analyzed a second time by the original analyst.

Asbestos · Lead · Mold

Gasper, John

From: [REDACTED]
Sent: Tuesday, March 09, 2010 5:31 PM
To: Gasper, John
Subject: Response to FDA
Attachments: FDA Sample Prep and Analysis.doc

Hi [REDACTED]

I wrote this up for us to send to FDA. It's a step by step preparation and analysis process. I figure if someone is requesting to know how we analyze the samples, we'll tell them EXACTLY how we do it. One thing we won't do is go into a detail description of optical and electron processes. We've done that a couple of times already. If the person with the FOI request wants to know what that is they can do the research themselves.

We got 7 more talc samples in today. They're logged in and in the oven already.

See you tomorrow.

[REDACTED]
[REDACTED]
Laboratory Director
4475 Forbes Blvd.
Lanham, Maryland 20706
1-800-346-0961

We are using a modified version of the NY State ELAP 198.6 / 198.4 method for the analysis of non-friable organically bound (NOB) samples.

General Preparation

- 1 Weigh the sample container
- 2 Add approximately 0.5 grams of sample to the container and weigh again.
- 3 Place the sample container into the muffle furnace, set at 480°C, for 12+ hours.
- 4 Remove the sample from the furnace and allow too cool to room temperature.
- 5 Weigh the sample. This is the post ash weight.
- 6 Weigh a Petri dish, a 5µm MCE filter and a 0.4µm PC filter. This is the tare.
- 7 Load a filtration unit with both filters. Make sure the 5µm filter is on the bottom.
- 8 Add hydrochloric acid (HCl) to the sample and allow too sit for 10 minutes.
- 9 Add 30ml of filtered water to the filtration unit.
- 10 Pore the acid treated sample into the filtration unit. Rinse the container several times to make sure all the sample is filtered.
- 11 Turn on the vacuum pump and rinse the sides of the filtration unit as the solution is drawn through the filter.
- 12 Place both filters in the pre-weighed Petri dish.
- 13 Place the Petri dish, containing the filters, in the drying oven for 30 minutes.
- 14 Take Petri dish out of the oven, allow too cool, and weigh.

PLM Preparation

- 15 In a hepa filtered hood prepare 4 slides for polarized light microscopy (PLM).

TEM Preparation

- 16 Place the top PC filter in a 100ml jar and add filter water to the 100ml line.
- 17 Place the jar in an ultrasonic bath for 5 minutes.
- 18 Assemble a filtration unit with a 5µm MCE bottom filter and a 0.22µm MCE Top filter.
- 19 Add 50 ml of filtered water to the filtration unit.
- 20 Shake the jar and pipette 0.2ml of the solution into the filtration unit.
- 21 Turn on the vacuum pump and filter the sample.
- 22 Place the 0.22µm MCE Top filter in a Petri dish and place it in the drying oven for 15 minutes.
- 23 Cut and collapse the filter, carbon coat it, cut it and place it on a TEM grid in dimethylformamide (DMF) solution. Leave the sample on the DMF for 2 hours.
- 24 Remove the sample from the DMF and place it in an acetone bath for 10 minutes.
- 25 Remove the sample from the acetone, allow a few seconds to dry, and place it in a labeled grid box.

PLM Analysis

- 26 Use the EPA 400 point count method for each sample.

- 27 For each fiber type encountered record all appropriate optical properties.
- 28 Using the recorded weight loss from the preparation process, calculate the percentage of fibrous components found.

TEM Analysis

- 29 Place the sample grid in the holder and insert the holder into the scope.
- 30 At magnifications between 4,800x and 19,000x, scan 20 grid openings.
- 31 If a fiber type is encountered check the selected area diffraction pattern (SAED) and the chemistry using electron dispersive x-ray analysis (EDXA)
- 32 Visually estimate the percentage of each fiber type.
- 33 Using the recorded weight loss from the preparation process, calculate the percentage of fibrous components found.

Quality Control

With each set of samples a “blank” sample is also prepared. This is a known negative source of talc (Sigma Aldrich Talc Powder, <10µm). This is analyzed as a routine sample. Finding asbestos in this sample would indicate contamination during the preparation process causing any positive result for customer samples to be suspect.

With each set of samples a reference sample is prepared. The reference sample is Sigma Aldrich Talc Powder, <10µm spiked with a known amount of NIST SRM 1866 Chrysotile. The sample is analyzed as a routine sample prior to analysis of the customer samples. It helps to calibrate the analyst’s visual estimate of asbestos in customer samples.

Replicate QC: At least 10% of all the samples are analyzed a second time by another analyst.

Duplicate QC: At least 2% of all samples are analyzed a second time by the original analyst.

Gasper, John

From: [REDACTED]
Sent: Wednesday, March 03, 2010 2:14 PM
To: [REDACTED] Gasper, John
Subject: FW: Fwd: Request for Talc Samples

So, Creations Colours is the 2nd company that has declined to play ball.

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[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

From: Alain Saintrond [mailto:asaintrond@yahoo.co.uk]
Sent: Wednesday, March 03, 2010 11:03 AM
To: [REDACTED]
Subject: Re: Fwd: Request for Talc Samples

Dear [REDACTED]

Then please get customer to ask us, direct.

Cordially.

Alain.

From: [REDACTED]
To: Alain Saintrond <asaintrond@yahoo.co.uk>
Sent: Wed, 3 March, 2010 15:37:59
Subject: RE: Fwd: Request for Talc Samples

Alain,

We have a client who has hired us to perform testing services on their behalf. They have specifically requested that we obtain samples of these materials from your organization for testing purposes.

Please do not hesitate to contact me with any additional questions or concerns that you may have.

Sincerely,

9/18/2012

[REDACTED]
From: [REDACTED] b6
Sent: Wednesday, March 03, 2010 1:23 AM
To: [REDACTED]
Subject: Fw: Fwd: Request for Talc Samples

Dear [REDACTED]

Please confirm why we should send you samples, as your are not a formulating company?

Cordially.

b6

----- Forwarded Message -----

From: Purchasing <purchasing@creationscouleurs.com>
To: [REDACTED] b6 <samples@creationscouleurs.com>
Sent: Tue, 2 March, 2010 19:16:17
Subject: Fwd: Request for Talc Samples

Begin forwarded message:

From: [REDACTED]
Date: 2 mars 2010 16:29:04 HNEC
To: <purchasing@creationscouleurs.com>
Subject: Request for Talc Samples

To Whom It May Concern:

I would like to request samples of 2 talc materials:

- 1) Talcpoly WL 10 PUR
- 2) Talcpoly WL 12 PUR

We will only need 4oz. samples. Please ship the materials to:

AMA Analytical Services
Attn: [REDACTED]
4475 Forbes Boulevard
Lanham, MD 20706, USA
(301) 459-2640/(800) 346-0961

Please do not hesitate to contact me with any questions or concerns that you may have.

I look forward to receiving the sample product.

Sincerely,
[REDACTED]

Gasper, John

From: [REDACTED] b6
Sent: Wednesday, March 03, 2010 9:38 AM
To: [REDACTED] b6
Subject: RE: Fwd: Request for Talc Samples

b6

We have a client who has hired us to perform testing services on their behalf. They have specifically requested that we obtain samples of these materials from your organization for testing purposes.

Please do not hesitate to contact me with any additional questions or concerns that you may have.

Sincerely,

From: [REDACTED] b6
Sent: Wednesday, March 03, 2010 1:23 AM
To: [REDACTED]
Subject: Fw: Fwd: Request for Talc Samples

Dear [REDACTED]

Please confirm why we should send you samples, as your are not a formulating company?

Cordially.

b6

----- Forwarded Message -----

From: Purchasing <purchasing@creationscouleurs.com>
To: [REDACTED] b6 <samples@creationscouleurs.com>
Sent: Tue, 2 March, 2010 19:16:17
Subject: Fwd: Request for Talc Samples

Begin forwarded message:

From: [REDACTED]
Date: 2 mars 2010 16:29:04 HNEC
To: <purchasing@creationscouleurs.com>
Subject: Request for Talc Samples

To Whom It May Concern:

9/18/2012

I would like to request samples of 2 talc materials:

- 1) Talcpoly WL 10 PUR
- 2) Talcpoly WL 12 PUR

We will only need 4oz. samples. Please ship the materials to:

AMA Analytical Services

Attn: [REDACTED]

4475 Forbes Boulevard

Lanham, MD 20706, USA

(301) 459-2640/(800) 346-0961

Please do not hesitate to contact me with any questions or concerns that you may have.

I look forward to receiving the sample product.

Sincerely,

[REDACTED]

Gasper, John

From: [REDACTED]
Sent: Friday, February 26, 2010 6:35 PM
To: Gasper, John
Subject: Talc results
Attachments: 197229 FDA.pdf

Hi John

The second set of talc results is attached. The data package will follow next week.

Thanks

[REDACTED]
[REDACTED]
Laboratory Director
4475 Forbes Blvd.
Lanham, Maryland 20706
1-800-346-0961

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Friday, February 26, 2010 5:58 PM
To: Gasper, John
Cc: [REDACTED]
Subject: 1st set of TALC Results
Attachments: 197155 FDA.pdf

Hi John,

Attached, please find the certificate of analysis for the first set of talc samples.

This is just the analytical report... we will work on the case narrative, data package, etc. next week. No asbestos was detected... in fact, no fibrous components were detected at all in this lot. We wanted to get this report out to you so that you could review the format and see if it met your needs.

Please give [REDACTED] a call next week once you and your team have had an opportunity to review the attached.

Also, I wanted to find out how things were going with the following:

- 1) Decision regarding talc products to be obtained from Whittaker, Clark & Davis/Brenntag.
- 2) Decision on how/if to proceed with Ultra Chemical, which is the one company thus far that is reluctant to send samples without us releasing more information regarding our client and our purposes.
- 3) Progress on the product list... we'd really like to get started with the products, even if you'll only be providing a partial list.

I look forward to hearing from you.

Thanks!!

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[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Tuesday, February 23, 2010 4:19 PM
To: Gasper, John
Subject: RE: Raw Cosmetic Grade Talc from Brenntag (Whittaker, Clark, & Daniels)

Thanks John... appreciate it. I'll give you a call on Thursday to discuss in more detail. Also, please let me know the status of the product list.

Thanks!!

AMA - Focused on Results!!

[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

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

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Tuesday, February 23, 2010 4:13 PM
To: [REDACTED]
Subject: RE: Raw Cosmetic Grade Talc from Brenntag (Whittaker, Clark, & Daniels)

66
I just wanted to let you know that this is still a high priority but it's because some members of the team are still out I don't have an answer yet. I'm hoping to get them all here in the next day or two. Thank you.

Regards,
John

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

From: [REDACTED]
Sent: Thursday, February 18, 2010 11:36 AM
To: Gasper, John
Subject: Raw Cosmetic Grade Talc from Brenntag (Whittaker, Clark, & Daniels)
Importance: High

John,

If you read below, you can see how our conversations with Brenntag have gone. They seem to think that 18 samples (their entire catalogue) is a rather large request and have asked us to narrow our selection based on application.

I had two thoughts in response to this situation:

1) offer to pay for the samples provided, but I think the less conversation we have with these suppliers, the better.

2) so we decided to go through their catalogue and choose several

samples that seem to be representative of their supply. I have highlighted our choices on the attached PDF file.

Please get back to me ASAP with instructions. At the moment, I've told Brenntag that I would have a final selection of materials by Monday.

Thanks!!

AMA - Focused on Results!!

[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
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(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

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

From: [REDACTED]@brenntag.com [mailto:[REDACTED]@brenntag.com]
Sent: Wednesday, February 17, 2010 4:12 PM
To: [REDACTED]
Subject: RE: Customer Set Up.
Importance: High

[REDACTED]
Is there any way you could speak to our technical manager [REDACTED]
[REDACTED],
x 4239) to narrow down the quantity of samples you will need. He can advise you which TALC's would be best. Please let me know.

Thanks in advance.

[REDACTED]
Customer Service Representative
Brenntag Specialties, Inc.
Ph: (800) 732- 0562 ext: 4258
Fx: (800) 543-1484
[REDACTED]@brenntag.com
www.brenntagsspecialties.com

To: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] [REDACTED]@brenntag.com>

cc 02/17/2010 04:06

PM

Subject

RE: Customer Set Up.

We would like samples of all talcs on the attached... shouldn't need more than 4oz each.

Thanks!!

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

From: [REDACTED]@brenntag.com [mailto:[REDACTED]@brenntag.com]
Sent: Wednesday, February 17, 2010 4:03 PM
To: [REDACTED]
Subject: RE: Customer Set Up.
Importance: High

You can give me the list of samples now so I can get all the product numbers ready. It will probably be a day or 2 before it is set up.

Thanks!

[REDACTED]
Customer Service Representative
Brenntag Specialties, Inc.
Ph: (800) 732- 0562 ext: 4258
Fx: (800) 543-1484
[REDACTED]@brenntag.com
www.brenntagsspecialties.com

To: [REDACTED]
[REDACTED] <[REDACTED]@brenntag.com>
cc: [REDACTED]
02/17/2010 03:44 PM
Subject: RE: Customer Set Up.

Hi [REDACTED]

Attached, please find completed copies of forms 5, 6, & 7.

Please let me know when we're set up in your system and I'll give you a list of materials that we would like samples of.

Please let me know if you need anything else.

Thanks!!

[REDACTED]
-----Original Message-----

From: [REDACTED]@brenntag.com [mailto:[REDACTED]@brenntag.com]

Sent: Tuesday, February 16, 2010 12:02 PM

To: [REDACTED]

Subject: Customer Set Up.

Hi [REDACTED]

Please fill out forms 5, 6 and 7. You do not need to send credit references at this time. But in the case you need material, we would need the references prior to your order. Once you have this information please email or fax it over and we can get your sample request going. Thanks in advance!

(See attached file: Credit 5 Multijurisdiction Sales.pdf) (See attached file: Credit 6 Customer Notification.pdf) (See attached file: Credit 7 Credit Agreement NJ.pdf) (See attached file: Credit 1 W-9.pdf) (See attached file: Credit 2 INS & SEC.pdf) (See attached file: Credit 4 Payment & Contact.pdf)

[REDACTED]
Customer Service Representative
Brenntag Specialties, Inc.
Ph: (800) 732- 0562 ext: 4258
Fx: (800) 543-1484

[REDACTED]@brenntag.com
www.brenntag specialties.com
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virus transmitted by this email or its attachments.
(See attached file: Brenntag_Credit 6 Customer Notification_AMA Analytical.pdf) (See attached file: Brenntag_Credit 7 Credit_Agreement NJ_AMA Analytical.pdf) (See attached file: Brenntag_Credit 5 Multijurisdiction Sales_AMA Analytical.pdf)DISCLAIMER AND NOTICE OF CONFIDENTIAL MATERIAL PLEASE READ This message and any attachments or other files transmitted with it are CONFIDENTIAL and intended solely for the use of the individual or entity to whom or to which they are addressed. If you are not the intended recipient, or believe you have received this email in error, please do not read, copy, use or disclose this communication to others; also please notify the sender by replying to this message, and then delete it and all accompanying files from your system. Please verify that you will delete the e-mail in your reply. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of Brenntag or its affiliated companies. Neither Brenntag nor any of its affiliated companies accepts any liability for any damage caused by any virus transmitted by this email or its attachments.
(See attached file: Talc_Cosmetic_Applications_US.pdf)DISCLAIMER AND NOTICE OF CONFIDENTIAL MATERIAL PLEASE READ This message and any attachments or other files transmitted with it are CONFIDENTIAL and intended solely for the use of the individual or entity to whom or to which they are addressed. If you are not the intended recipient, or believe you have received this email in error, please do not read, copy, use or disclose this communication to others; also please notify the sender by replying to this message, and then delete it and all accompanying files from your system. Please verify that you will delete the e-mail in your reply. Please note that any views or opinions presented in this email are solely those of the author and do not necessarily represent those of Brenntag or its affiliated companies. Neither Brenntag nor any of its affiliated companies accepts any liability for any damage caused by any virus transmitted by this email or its attachments.

Gasper, John

From: [REDACTED]
Sent: Monday, February 22, 2010 5:20 PM
To: Gasper, John
Subject: Personel handling samples
Attachments: [REDACTED] Resume.doc

Hi John

When we bid the contract we had to submit to you the names of the analysts doing the samples. I would like to add one more analyst to the list. Her name is [REDACTED] She is a PLM analyst. Her resume is attached.

Thanks

[REDACTED]
[REDACTED]
Laboratory Director
4475 Forbes Blvd.
Lanham, Maryland 20706
1-800-346-0961

9/18/2012



AMA Analytical Services, Inc.

A Specialized Environmental Laboratory



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66

Position: Laboratory Analyst/Optical Microscopist

Education: B.S., Geology, University of Maryland, December 1989

Professional Experience: AMA Analytical Services, Inc. (February 2008 – Present)

66 is an asbestos analyst with AMA Analytical Services, Inc. She is trained and experienced in the analysis of asbestos samples by Polarized Light Microscopy (PLM).

CSA / Pro Quest (1994 – Present)
Managing Editor

AMA Analytical Services, Inc. (1991 – 1994)
Optical Microscopist (PLM, PCM)

OMC Environmental, Inc. (1989-1991)
Optical Microscopist (PLM, PCM)

Special Training: NIOSH 582 – “Sampling & Evaluating Airborne Asbestos Dust,” OMC Environmental (1990)

McCrone Research Institute – “Microscopical Identification of Asbestos” (May 1991)

Asbestos • Lead • Mold

Gasper, John

From: [REDACTED]
Sent: Thursday, February 18, 2010 3:20 PM
To: Gasper, John
Subject: RE: Mailing Address for John Gasper - FDA
Attachments: Invoice.pdf

Hi John,

Thanks for providing that address... the attached PDF file is sample of how your address will appear on all paperwork generated by AMA in relation to this contract.

Although this same address will appear on all invoices, they will get mailed to the following address as per the PO:
DHHS/FDA/Accounting Operations Branch
12345 Parklawn Drive
HFA-720
Rockville, MD 20857

Thanks!!

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[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile
[REDACTED]
www.amalab.com

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Thursday, February 18, 2010 2:43 PM
To: [REDACTED]
Subject: Mailing Address for John Gasper - FDA

Hi [REDACTED]

Here's my mailing address:

5100 Paint Branch Pkwy
Univ. Station, Rm. 1037
HFS-125
College Park, MD 20740

Regards,
John

9/18/2012



AMA Analytical Services, Inc.



Invoice:

Client: Food & Drug Administration - Cosmetics & Colors
Job Name: Raw Cosmetic Grade Talc
Chain Of Custody: 197155
Address: 5100 Paint Branch Parkway
Job Location: Samples Provided by Presperse
Date Submitted: 2/18/2010
University Station, Room 1037 - HFS 125
Job Number: Not Provided
Date Analyzed:
College Park, Maryland
P.O. Number: HHSF223200910466P
Date Invoiced:
20740
Person Submitting: Presperse

Attention: John Gasper

Page 1 of 2

AMA Sample #	Client Sample #	Analysis and Sample Type	Turn Around	Cost	Additional Analysis and Sample Type *	Turn Around *	Additional Cost *	Total Cost
1026717	Micro Ace P-2 Lot #33070516 - A	PLM ELAP 198.6 NOB	5 Day +	b4	TEM ELAP 198.4	5 Day +	b4	
1026718	Micro Ace P-4 Lot #37080823 - A	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026719	Rose Talc Lot#2008-09 - A	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026720	Talc NK-48 Lot#017 0306 - A	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026721	TalClear BH Lot#070608 - A	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026722	TalClear LH Lot#070529 - A	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026770	Micro Ace P-2 Lot #33070516 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026771	Micro Ace P-2 Lot #33070516 - C	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026772	Micro Ace P-4 Lot #37080823 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026773	Micro Ace P-4 Lot #37080823 - C	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026774	Rose Talc Lot#2008-09 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026775	Rose Talc Lot#2008-09 - C	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026776	Talc NK-48 Lot#017 0306 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		

Note: Payment Due Upon Receipt.

Note: All Accounts over 30 days are subject to a 1½% per month service charge.

* Only apply if additional analysis was performed on the sample(s)

Account Code: FDATA LC

Remit to: P.O. Box 646, Hanover, Maryland 21076, 410-684-3327



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Page 2 of 2

AMA Sample #	Client Sample #	Analysis and Sample Type	Turn Around	Cost	Additional Analysis and Sample Type *	Turn Around *	Additional Cost *	Total Cost
1026777	Talc NK-48 Lot#017 0306 - C	PLM ELAP 198.6 NOB	5 Day +	b4	TEM ELAP 198.4	5 Day +	b4	
1026778	TalClear BH Lot#070608 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026779	TalClear BH Lot#070608 - C	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026780	TalClear LH Lot#070529 - B	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		
1026781	TalClear LH Lot#070529 - C	PLM ELAP 198.6 NOB	5 Day +		TEM ELAP 198.4	5 Day +		

Sub-Total:
Additional Charge: (b)(4)
Total:

Note: Payment Due Upon Receipt.

Note: All Accounts over 30 days are subject to a 1½% per month service charge.

* Only apply if additional analysis was performed on the sample(s)

Account Code: FDATALC

Remit to: P.O. Box 646, Hanover, Maryland 21076, 410-684-3327

Gasper, John

From: [REDACTED]
Sent: Thursday, February 18, 2010 11:36 AM
To: Gasper, John
Subject: Raw Cosmetic Grade Talc from Brenntag (Whittaker, Clark, & Daniels)
Importance: High
Attachments: Brenntag_Cosmetic Talc Catalogue.pdf



Brenntag_Cosm
etic Talc Catalog..

John,

If you read below, you can see how our conversations with Brenntag have gone. They seem to think that 18 samples (their entire catalogue) is a rather large request and have asked us to narrow our selection based on application.

I had two thoughts in response to this situation:

- 1) offer to pay for the samples provided, but I think the less conversation we have with these suppliers, the better.
- 2) so we decided to go through their catalogue and choose several samples that seem to be representative of their supply. I have highlighted our choices on the attached PDF file.

Please get back to me ASAP with instructions. At the moment, I've told Brenntag that I would have a final selection of materials by Monday.

Thanks!!

AMA - Focused on Results!!

[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile
[REDACTED]

www.amalab.com

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

From: [REDACTED]@brenntag.com [mailto:[REDACTED]@brenntag.com]
Sent: Wednesday, February 17, 2010 4:12 PM
To: [REDACTED]
Subject: RE: Customer Set Up.
Importance: High

[REDACTED]
Is there any way you could speak to our technical manager [REDACTED] x 4239) to narrow down the quantity of samples you will need. He can advise you which TALC's would be best. Please let me know.

Thanks in advance.

ApplicationData

BRENNTAG
SPECIALTIES

Cosmetic Talcs - Application Guide



Product Code & Name	Cosmetic (CTFA)	USP	EP / BP	FCC	JP	Median Particle Size (typical) Micron	Loose Bulk Density (typical) lb/ft ³	Brightness ("Y") (typical) %	Aerosols	Press Powders	Loose Powders	Lotions & Creams	Pencils Lipsticks Sticks	Founda- tions	Anti- Perspirant
WCD 2755	•	•				1	7.5	90	•						
194 Pharma M		•	•		•	4.7	17.5	92.5		•			•	•	
195 (Superior M/10 Dec)	•					4	13.7	94.5		•			•	•	
Whittaker IMP 1884 L	•					4	11.8 - 16.8	> 88	•					•	
Whittaker IMP 1885 L	•	•				4	14 - 18	> 88	•	•				•	
Whittaker IMP 1886 L	•					4	14 - 19	> 88	•	•		•	•	•	
Whittaker IMP 1887 L	•					4	12.7 - 19	> 87	•					•	
Whittaker IMP 1889 L	•	•	•			4	14 - 18	> 90		•				•	•
3478H (Imperial 400)	•					5	14	91		•			•	•	
3460 H (Suprafino H)	•					5	15.9	95		•			•	•	

Information presented herein is believed to be accurate and reliable but is not intended to meet any specification and does not imply any guarantee or warranty by Brenntag Specialties, Inc. (BSI). For more information and assistance, contact Technical Services at 1-800-732-0562.

• Brenntag Specialties, Inc. • 1000 Coolidge St. • South Plainfield, NJ 07080 •



ApplicationData

BRENTAG
SPECIALTIES

Cosmetic Talcs - Application Guide - (Continued)



Product Code & Name	Cosmetic (CTFA)	USP	EP / BP	FCC	Median Particle Size (typical)	Loose Bulk Density (typical)	Brightness ("Y") (typical)	Aerosols	Press Powders	Loose Powders	Lotions & Creams	Pencils Lipsticks Sticks	Founda- tions	Shaving Products	Anti- Perspirant
					Micron	lb/ft ³	%								
WCD 1745	•	•			6	21.8	88		•						
5210H (Supreme H)	•				7	21.8	93	•		•	•				
5215H (Olympic H)	•				11	25.8	93			•					
Whittaker IMP 1820 L	•				11	25 - 29	> 88		•	•	•			•	•
Whittaker IMP 1821 L	•				11	25.8 - 30.8	> 87		•	•					•
Whittaker IMP 1822 L	•				11	22.7 - 33	>87		•	•					
3465H (Supra H)	•				12	25.8	94		•	•	•		•		•
190 (Extra 5/0 Dec)	•				12	27.4	91			•					
3476H (Imperial 2 0)	•				14	33	88			•					

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Gasper, John

From: [REDACTED]
Sent: Tuesday, February 16, 2010 1:28 PM
To: Gasper, John
Subject: Talc Supplier requesting Additional information

Hi John,

I hope you guys enjoyed your snow week ☺

I'm spending the day today obtaining samples from various suppliers, which in some cases in turning out to be a more involved process than I had originally anticipated.

I spoke with Ultra Chemical in NJ, and their representative was "a little leery" of sending us samples of material without us providing additional information. My conversation went something like this:

- a. They have 5 grades for cosmetic application
- b. Does not feel comfortable sending out samples without some additional information... is "a little leery." They have nothing to hide and understand client confidentiality, testing, etc. but doesn't want to send samples to a potential competitor... perhaps if we could tell him the type of company our client is (chemical, cosmetic, etc.). In his opinion that wouldn't violate confidentiality.
- c. My response was: "I have a confidentiality agreement that does not allow me to release information regarding my client. We have been asked to obtain samples of cosmetic grade talc from certain companies for testing purposes. I will talk to my bosses here to learn if there is any additional information that we can release regarding our client and their purposes."

I leave it up to the FDA to decide if we should pursue obtaining sample material from this organization or not. If so, please let me know what other information I can release to them.

Thanks!!

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[REDACTED]
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9/18/2012

Gasper, John

From: [REDACTED]
Sent: Friday, January 29, 2010 10:55 AM
To: Gasper, John; [REDACTED] 66
Cc: Bronaugh, Robert L
Subject: RE: Asbestos in Talc Analysis
Attachments: Analytical Criteria_Positive ID.pdf

John,

Attached, please find our response to this question. As an addendum, we've attached a simple chart describing the optical properties of the 6 regulated asbestiform minerals, which was taken from the NY ELAP Method 198.1.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thanks!!

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From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Tuesday, January 26, 2010 3:22 PM
To: [REDACTED]
Cc: Bronaugh, Robert L
Subject: Asbestos in Talc Analysis

[REDACTED]
A question has arisen here concerning analytical criteria and we'd like to know what specific criteria do you use to positively identify a particle as being asbestos. For example, what particle length and aspect ratio would qualify a particle as being asbestos. Thank you.

Regards,
John Gasper
OCAC
FDA

9/18/2012

Gasper, John

From: [REDACTED]
Sent: Thursday, January 07, 2010 4:32 PM
To: Gasper, John; [REDACTED]
Cc: Hansen, Patricia A; Bronaugh, Robert L; Havery, Donald C; Hurley, Fred J
Subject: RE: Questions & Clarifications from AMA Analytical - Asbestosform Analysis of Cosmetic Talc
Attachments: Questions and Clarifications with FDA Responses and AMA responses.pdf

John,

Attached, please find our responses to your additional questions... I combined the information into one document so it would be easier to see all the information exchanged thus far. Our responses to your questions begin on page 2 of the document.

Two main things...

- 1) Kick-off meeting – we would like to hold the meeting here in our office... we propose the following dates:
 - a. Tuesday, January 12, 2010 at 10:30AM
 - b. Thursday, January 14, 2010 at 10:30AM
 - c. Tuesday, January 19, 2010 at 10:30AM
 - d. Thursday, January 21, 2010 at 10:30AM
 - e. Tuesday, January 26, 2010 at 10:30AM
 - i. Please let us know which of the above would be most convenient for you. Please also let us know how many people from your team will be attending.
- 2) You mention that you have a list of suppliers for the raw cosmetic grade materials as well as a partial list of products right now. We would like to request that this information be forwarded to us ASAP so that we can get started on obtaining the materials.

I look forward meeting with you and your team. Please let me know as soon as possible when we can schedule it.

Please do not hesitate to contact me with any additional questions or concerns that you may have.

Thanks!!

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(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

9/18/2012

From: Gasper, John [mailto:John.Gasper@fda.hhs.gov]
Sent: Monday, January 04, 2010 2:49 PM
To: [REDACTED]
Cc: Hansen, Patricia A; Bronaugh, Robert L; Havery, Donald C; Hurley, Fred J
Subject: RE: Questions & Clarifications from AMA Analytical - Asbestosform Analysis of Cosmetic Talc

66

Please find attached our responses to your questions along with several questions we have as well. We look forward to meeting your people soon. As far as scheduling a meeting, please let me know what dates and times would be most convenient for you so that I can check them versus our groups availability. Thank you.

Regards,
John Gasper
Office of Cosmetics and Colors
FDA

From: [REDACTED]
Sent: Wednesday, October 14, 2009 5:40 PM
To: Gasper, John
Cc: [REDACTED]
Subject: Questions & Clarifications from AMA Analytical - Asbestosform Analysis of Cosmetic Talc

John,

Per our conversation, I've attached a list of questions and clarifications regarding the above referenced project.

We look forward to receiving the FDA's response and getting started.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thanks!!

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Questions/Clarifications

FDA-09-1061335 – Asbestosform Analysis in Cosmetic Talc

- 1) The SOW for this project states “The Contractor shall identify appropriate laboratory analytical methods and consult with the Project Officer in making the final selection of methods to be used in the survey.”

- a. Would the Project Officer like to schedule a time to meet with our Vice President and Laboratory Director, [REDACTED]

Yes, we would like to meet and discuss the project with your Laboratory Director, [REDACTED]. We anticipate discussing method development.

- 2) The burning process during gravimetric reduction is typically conducted at 480 degrees C. Depending on the matrix of the sample being analyzed, there may be concerns with regards flammability, especially if any of the materials to be analyzed are oil based.

- a. Are any of the materials flammable at 480 degrees C?
b. Are any of the materials oil based?

Yes, some of the samples may be flammable at 480C and some may be oil based.

- 3) It is our understanding that we will be analyzing both bulk raw material and talc-containing cosmetic products that are already available on the market.

- a. Will the FDA provide the bulk raw material or will AMA need to obtain the material on our own?
i. If AMA will need to obtain the raw material on our own, will FDA provide the contact information for suppliers?

AMA will need to purchase the bulk raw material and FDA will provide a list of raw material suppliers. AMA will have to carefully formulate the wording of purchase requests to ensure that we don't get industrial grade talc. For example, AMA should request only talc that the supplier sells that is consistent with use in cosmetic products.

- b. Will the FDA provide a list of products already on the market that it would like tested?

We can give a partial list at this time and will decide on other products to test in the near future.

- c. When does the FDA anticipate being able to finalize this list?

It will probably take a few weeks to determine the entire list of products.

- d. Once the list is provided to AMA, how much time will we have to obtain those materials?

Since the samples to be tested are available at common retail stores, it should only take a couple of weeks to find and purchase them. If there are any problems please contact us.

- e. Are all of the materials sold in the US?

Yes, all materials are sold in the U.S.

- 4) It is our understanding that 78 materials are to be tested in triplicate, totaling 234 analyses.

- a. Bulk Raw Material

- i. Will we need to procure 3 batches of each source material or will we simply need to prepare 3 aliquots per batch?

Prepare 3 aliquots per batch (analyze each sample in triplicate).

- b. Talc Containing Cosmetic Products



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- i. Will we need to procure 3 packages/product or will we simply need to prepare 3 aliquots from each package?

Prepare 3 aliquots per package/product (analyze each sample in triplicate).

- c. Is it likely that the FDA will request additional materials to be analyzed?

- i. When can AMA expect the FDA to make this decision?

If there is time remaining in the contract, we'll define more samples to be analyzed.

- 5) The SOW for this project states "The Contractor shall provide interim reports at 3 month intervals on the results of analysis...."

- a. Does the FDA have a more specific time-line that it would like to provide?

We don't have a more specific time line to follow on reporting results. Just report every three months on what you have accomplished.

- b. How would the FDA like results to be organized?

- i. Certificate of Analysis on a per material basis?
 - ii. Certificate of Analysis for all materials analyzed within a given time-frame?
 - iii. Some combination of these, i.e. a Certificate of Analysis for all bulk raw material within a given timeframe, a Certificate of Analysis for all cosmetic products within a given timeframe, and/or a Certificate of Analysis for all cosmetic products of a particular brand within a given timeframe?

Basically, we want all the analytical data you generate that relates to fibrous minerals along with your interpretation of the data. For example, we want the following information:

- All data associated with products identified as containing asbestos along with the basis for this determination
- photomicrographs of fibrous minerals identified by PLM with identification, if possible
- photomicrographs of fibrous minerals identified by TEM and associated SAED patterns with interpretations

- 6) Does the FDA have a required minimum level of quantitation?

- a. Quantitation levels can vary depending on the nature of the material and the amount of material lost during gravimetric reduction.

We would like the lowest level of quantitation possible consistent with the achievable limit of quantitation. We don't want to create a research project out of every sample. This is also why we want you to analyze the easy samples first and the more complex samples later. (i.e. start with simple matrix products and then complex matrix products later.)

Additional questions posed by FDA:

- A) How do you calibrate your TEM microscope to insure that SAED data collected is reliable since this is the basis for asbestos identification?
 - a. We perform a monthly SAED calibration of both of our TEM scopes using a gold standard, which produces a measureable ring pattern. This is the standard way to calibrate SAED for asbestos analysis and is required by NIST/NVLAP.



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- B) How do you establish homogeneity of the sample matrix being analyzed?
- The material is visually examined using a stereomicroscope at 4-40x magnification to look for subtle differences in texture and color within the sample in order to gauge its initial homogeneity, and to determine the best techniques to use should the sample require further homogenization.
 - If the sample can be crushed and reduced to a powder, a representative portion of the material is transferred to a mortar and pestle. It is then crushed and mixed to produce a well homogenized powder. Aliquots of this powder may then be prepared for analysis.
 - If the material cannot easily be reduced to a powder, such as wax or tar based samples, additional steps are taken to obtain homogenous aliquots of the sample for analysis.
 - The sample may be frozen using a small amount of liquid nitrogen and then crushed and mixed using the mortar and pestle.
 - If the sample cannot be reduced to a powder even after freezing, the micro-sampling technique can be used to obtain a suitable aliquot for analysis.
 - This technique involves using tweezers or forceps to take many small pieces of the sample from many areas of the samples. This technique, when done under stereomicroscopic viewing, usually produces a representative aliquot for analysis.
 - If, in the analyst's opinion, the micro-sampling technique cannot produce a suitable aliquot, a large portion of the sample, or, in extreme cases, the entire sample, may be ashed in a muffle furnace. The residual ash may then be mixed and an aliquot of the ash taken for further preparation and analysis.
- C) What do you use as a standard to measure samples against? We believe that this is extremely important and that AMA will need to obtain an official talc standard to calibrate the TEM microscope against. An official talc standard is necessary to calibrate the TEM microscope so that the SAED pattern obtained is the SAED pattern for talc. Otherwise, any findings identifying non-talc fibers will be considered unreliable because we didn't have a reliable standard for comparison. Perhaps this can be obtained from Sigma/Aldrich or USGS.
- Neither NIST nor USGS has a talc standard. Sigma Aldrich, however, does. We are purchasing 2 different talc reference materials from them. The following links provide specific details for each standard:
http://www.sigmaaldrich.com/catalog/ProductDetail.do?lang=en&N4=243604|SIAL&N5=SEARCH_CONCAT_PNO|BRAND_KEY&F=SPEC
http://www.sigmaaldrich.com/catalog/ProductDetail.do?lang=en&N4=18654|SIAL&N5=SEARCH_CONCAT_PNO|BRAND_KEY&F=SPEC
- D) We would also like to discuss further your overall sampling plan and procedures.
- We look forward to our "kick-off" meeting. If at all possible, we would like to conduct that meeting here in our laboratory. That way, you can tour our facilities and it may make it easier to address questions and/or concerns that you may have.
 - We propose the following dates and times:



AMA Analytical Services, Inc.

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- i. Tuesday, January 12, 2010 at 10:30AM
 - ii. Thursday, January 14, 2010 at 10:30AM
 - iii. Tuesday, January 19, 2010 at 10:30AM
 - iv. Thursday, January 21, 2010 at 10:30AM
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Additional Comments from AMA:

- 1) You mention that you have a list of suppliers for the raw cosmetic grade materials as well as a partial list of products right now. We would like to request that this information be forwarded to us ASAP so that we can get started on obtaining the materials.

Gaspar, John

From: [REDACTED]
Sent: Friday, September 25, 2009 4:06 PM
To: Alexander-Giles, Linda; Gaspar, John; Miller, George C
Cc: Bumbray, Jose; Syntoria_Spencer@nbc.gov
Subject: RE: Scanned document from Linda.Alexander
Attachments: Signed Talc PO.pdf

Attached, please find a signed copy of the purchase order.

Please do not hesitate to contact me with any questions or concerns that you may have.

Thanks!!

AMA - Focused on Results!!



[REDACTED]
Director of Client Services
AMA Analytical Services, Inc.
4475 Forbes Boulevard
Lanham, MD 20706
(301) 459-2640/(800) 346-0961
(301) 459-2643 Fax
(410) 562-9699 Mobile

[REDACTED]
www.amalab.com

From: Alexander-Giles, Linda [mailto:Linda.Alexander-Giles@fda.hhs.gov]
Sent: Friday, September 25, 2009 1:22 PM
To: Gaspar, John; Miller, George C
Cc: [REDACTED]
Subject: FW: Scanned document from Linda.Alexander

Attached is the purchase order for the talc samples laboratory testing.

Linda Alexander-Giles
Contracting Officer
Office of Acquisition and Grants
System Technology Acquisition Team
Office: 301-827-7048
Fax: 301-827-7039

<<466PScanDoc.PDF>>

9/18/2012

SOLICITATION/CONTRACT/ORDER FOR COMMERCIAL ITEM				1. REQUISITION NUMBER 1061335		PAGE OF 1 13	
2. CONTRACT NO.				3. AWARD/ EFFECTIVE DATE		4. ORDER NUMBER HHSF223200910466P	
5. SOLICITATION NUMBER				6. SOLICITATION ISSUE DATE			
7. FOR SOLICITATION INFORMATION CALL:		a. NAME JOSE BUMBRAY		b. TELEPHONE NUMBER 301-827-9215		8. OFFER DUE DATE/LOCAL TIME	
9. ISSUED BY DHHS/FDA/OAGS/DCSC ATTN: Jose Bumbray 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857				10. THIS ACQUISITION IS ☒ UNRESTRICTED OR ☐ SET ASIDE: % FOR: ☐ SMALL BUSINESS ☐ EMERGING SMALL BUSINESS ☐ HUBZONE SMALL BUSINESS ☐ SOLE SOURCE ☐ SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS ☐ 8(A) NAICS: SIZE STANDARD:			
11. DELIVERY FOR FOB DESTINATION UNLESS BLOCK IS MARKED ☐ SEE SCHEDULE		12. DISCOUNT TERMS IHS NET 30		13a. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		13b. RATING	
15. DELIVER TO 4300 RIVER ROAD 4300 RIVER ROAD COLLEGE PARK MD 20770				16. ADMINISTERED BY DHHS/FDA/OAGS/DCSC ATTN: Jose Bumbray 5630 FISHERS LANE ROOM 2129, HFA-500 ROCKVILLE MD 20857			
17a. CONTRACTOR/ OFFEROR		CODE 286421		FACILITY CODE		18a. PAYMENT WILL BE MADE BY DHHS/FDA/Accounting Operations Br. ATTN: 12345 PARKLAWN DRIVE HFA-720 301-827-3742 OR 866-807-3742 ROCKVILLE MD 20857	
17b. CHECK IF REMITTANCE IS DIFFERENT AND PUT SUCH ADDRESS IN OFFER				18b. SUBMIT INVOICES TO ADDRESS SHOWN IN BLOCK 18a UNLESS BLOCK BELOW IS CHECKED ☐ SEE ADDENDUM			
19. ITEM NO.		20. SCHEDULE OF SUPPLIES/SERVICES		21. QUANTITY		22. UNIT	
		Tax ID Number: 52-1547768 DUNS Number: 196508139 Laboratory survey services for talc-containing products Delivery: 09/27/2010 Appr. Yr.: 2009 CAN: 6991712 Object Class: 252K CenterTag: 31420GMOCAC1045 Period of Performance: 09/28/2009 to 09/27/2010 Continued ... (Use Reverse and/or Attach Additional Sheets as Necessary)					
						23. UNIT PRICE	
						24. AMOUNT	
25. ACCOUNTING AND APPROPRIATION DATA 2009-6991712-252K-31420GMOCAC1045				26. TOTAL AWARD AMOUNT (For Govt. Use Only) \$98,748.00			
27a. SOLICITATION INCORPORATES BY REFERENCE FAR 52.212-1, 52.212-4, FAR 52.212-3 AND 52.212-5 ARE ATTACHED. ADDEND ☐ ARE ☐ ARE NOT ATTACHED.				27b. CONTRACT/PURCHASE ORDER INCORPORATES BY REFERENCE FAR 52.212-4, FAR 52.212-5 IS ATTACHED. ADDENDA ☐ ARE ☐ ARE NOT ATTACHED.			
28. CONTRACTOR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN COPIES TO ISSUING OFFICE. CONTRACTOR AGREES TO FURNISH AND DELIVER ALL ITEMS SET FORTH OR OTHERWISE IDENTIFIED ABOVE AND ON ANY ADDITIONAL SHEETS SUBJECT TO THE TERMS AND CONDITIONS SPECIFIED HEREIN.				29. AWARD OF CONTRACT REF. _____ OFFER DATED _____. YOUR OFFER ON SOLICITATION (BLOCK 5), INCLUDING ANY ADDITIONS OR CHANGES WHICH ARE SET FORTH HEREIN, IS ACCEPTED AS TO ITEMS:			
30a. SIGNATURE OF OFFEROR/CONTRACTOR				31a. UNITED STATES OF AMERICA (SIGNATURE OF CONTRACTING OFFICER) <i>Linda Alexander-Giles</i>			
30b. NAME AND TITLE OF SIGNER (Type or print) Director of Client Services				30c. DATE SIGNED 9/25/2009		31b. NAME OF CONTRACTING OFFICER (Type or print) Linda Alexander-Giles	
						31c. DATE SIGNED 9-25-09	

19. ITEM NO.	20. SCHEDULE OF SUPPLIES/SERVICES	21. QUANTITY	22. UNIT	23. UNIT PRICE	24. AMOUNT
1	Laboratory Survey Services 1. The total cost to process 78 talc-containing products in triplicate to determine asbestiform materials about 234 analyses is a fixed price of \$40,000. 2. Indefinite Delivery Indefinite Quantity Line Item - Work under this CLIN shall not exceed the funding amount of \$58,748.00. The period of performance shall commence from the period beginning contract award through twelve (12) months thereafter. At the discretion of the Contracting Officer, the Government may use a the IDIQ line item for the contractor to purchase raw cosmetic grade talc and cosmetic products for analysis beyond the estimated 78 samples and to be reimbursed for costs incurred in the performance of the task orders to include labor and materials or a combination thereof. Each additional Request Task Order Proposal (RTOP) will be issued under the IDIQ line item. 52.252-2 Clauses Incorporated By Reference (Feb 1998) Continued ...				98,748.00

32a. QUANTITY IN COLUMN 21 HAS BEEN

☐ RECEIVED☐ INSPECTED

ACCEPTED, AND CONFORMS TO THE CONTRACT, EXCEPT AS

☐ NOTED:

32b. SIGNATURE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32c. DATE

32d. PRINTED NAME AND TITLE OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32e. MAILING ADDRESS OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32f. TELEPHONE NUMBER OF AUTHORIZED GOVERNMENT REPRESENTATIVE

32g. E-MAIL OF AUTHORIZED GOVERNMENT REPRESENTATIVE

33. SHIP NUMBER

34. VOUCHER NUMBER

35. AMOUNT VERIFIED
CORRECT FOR

36. PAYMENT

37. CHECK NUMBER

☐ PARTIAL ☐ FINAL☐ COMPLETE ☐ PARTIAL ☐ FINAL

38. S/R ACCOUNT NUMBER

39. S/R VOUCHER NUMBER

40. PAID BY

41a. I CERTIFY THIS ACCOUNT IS CORRECT AND PROPER FOR PAYMENT

42a. RECEIVED BY (Print)

41b. SIGNATURE AND TITLE OF CERTIFYING OFFICER

41c. DATE

42b. RECEIVED AT (Location)

42c. DATE REC'D (YY/MM/DD)

42d. TOTAL CONTAINERS

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): http://www.arnet.gov 52.212-4 Contract Terms and Conditions-Commercial Items (Mar 2009) 52-212-5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders -- Commercial Items (Sep 2009) (a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items: ___ (1) 52.222-50, Combating Trafficking in Persons (FEB 2009) (22 U.S.C. 7104(g)). ___ (2) 52.233-3, Protest After Award (AUG 1996) (31 U.S.C. 3553). ___ (3) 52.233-4, Applicable Law for Breach of Contract Claim (OCT 2004) (Pub. L. 108-77, 108-78). (b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the contracting officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items: ___ (1) 52.203-6, Restrictions on Subcontractor Sales to the Government (Sep 2006), with Alternate I (Oct 1995) (41 U.S.C. 253g and 10 U.S.C. 2402). ___ (2) 52.203-13, Contractor Code of Business Ethics and Conduct (Dec 2008) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 251 note)). ___ (3) 52.203-15, Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (Section 1553 of Pub L. 111-5). ___ (4) 52.204-11, American Recovery and Reinvestment Act-Reporting Requirements (Mar 2009) (Pub. L. 111-5). ___ (5) 52.219-3, Notice of Total HUBZone Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Set-Aside (Jan 1999) (15 U.S.C. 657a). ___ (6) 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Jul 2005) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a). ___ (7) [Reserved] ___ (8) (i) 52.219-6, Notice of Total Small Business Aside (June 2003) (15 U.S.C. 644). ___ (ii) Alternate I (Oct 1995) of 52.219-6. ___ (iii) Alternate II (Mar 2004) of 52.219-6. ___ (9) (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644). ___ (ii) Alternate I (Oct 1995) of 52.219-7. ___ (iii) Alternate II (Mar 2004) of 52.219-7. ___ (10) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d)(2) and (3)). ___ (11) (i) 52.219-9, Small Business Subcontracting Plan (Apr 2008) (15 U.S.C. 637(d)(4)). ___ (ii) Alternate I (Oct 2001) of 52.219-9. ___ (iii) Alternate II (Oct 2001) of 52.219-9. ___ (12) 52.219-14, Limitations on Subcontracting (Dec 1996) (15 U.S.C. 637(a)(14)). ___ (13) 52.219-16, Liquidated Damages Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)). ___ (14) (i) 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (Oct 2008) (10 U.S.C. 2323) (if the offeror elects to waive the adjustment, it shall so indicate in its offer). ___ (ii) Alternate I (June 2003) of 52.219-23. ___ (15) 52.219-25, Small Disadvantaged Business Participation Program-Disadvantaged Status and Reporting (Apr 2008) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323). ___ (16) 52.219-26, Small Disadvantaged Business Participation Program-Incentive Subcontracting (Oct 2000) (Pub. L. 103-355, section 7102, and 10 U.S.C. 2323). ___ (17) 52.219-27, Notice of Total Service-Disabled Veteran-Owned Small Business Set-Aside (May 2004) (15 U.S.C. 657 f). _x_ (18) 52.219-28, Post Award Small Business Program Rerepresentation (Apr 2009) (15 U.S.C. 632(a)(2)). Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	☒ (19) 52.222-3, Convict Labor (June 2003) (E.O. 11755). ☒ (20) 52.222-19, Child Labor Cooperation with Authorities and Remedies (Feb 2008) (E.O. 13126). ☒ (21) 52.222-21, Prohibition of Segregated Facilities (Feb 1999). ☒ (22) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246). ☐ (23) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006) (38 U.S.C. 4212). ☒ (24) 52.222-36, Affirmative Action for Workers with Disabilities (Jun 1998) (29 U.S.C. 793). ☐ (25) 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (Sep 2006) (38 U.S.C. 4212). ☐ (26) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201). ☐ (27) 52.222-54, Employment Eligibility Verification (Jan 2009). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.) ☐ (28) (i) 52.223-9, Estimate of Percentage of Recovered Material Content for EPA-Designated Items (May 2008) (42 U.S.C. 6962(c) (3) (A) (ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.) ☐ (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i) (2) (C)). (Not applicable to the acquisition of commercially available off-the-shelf items.) ☐ (29) 52.223-15, Energy Efficiency in Energy-Consuming Products (Dec 2007) (42 U.S.C. 8259b). ☐ (30) (i) 52.223-16, IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products (Dec 2007) (E.O. 13423). ☐ (ii) Alternate I (Dec 2007) of 52.223-16. ☐ (31) 52.225-1, Buy American Act--Supplies (Feb 2009) (41 U.S.C. 10a-10d). ☐ (32) (i) 52.225-3, Buy American Act ?Free Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Trade Agreements ? Israeli Trade Act (Feb 2009) (41 U.S.C. 10a-10d, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, Pub. L. 108-77, 108-78, 108-286, and 109-169). ___ (ii) Alternate I (Jan 2004) of 52.225-3. ___ (iii) Alternate II (Jan 2004) of 52.225-3. ___ (33) 52.225-5, Trade Agreements (Mar 2009) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note). ___ (34) 52.225-13, Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury). ___ (35) 52.226-4, Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150). ___ (36) 52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150). ___ (37) 52.232-29, Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)). ___ (38) 52.232-30, Installment Payments for Commercial Items (Oct 1995) (41 U.S.C. 255(f), 10 U.S.C. 2307(f)). ___ x (39) 52.232-33, Payment by Electronic Funds Transfer Central Contractor Registration (Oct. 2003) (31 U.S.C. 3332). ___ (40) 52.232-34, Payment by Electronic Funds Transfer?Other Than Central Contractor Registration (May 1999) (31 U.S.C. 3332). ___ (41) 52.232-36, Payment by Third Party (May 1999) (31 U.S.C. 3332). ___ x (42) 52.239-1, Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a). ___ (43) (i) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). ___ (ii) Alternate I (Apr 2003) of 52.247-64. (c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or executive orders applicable to acquisitions of commercial items: Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	[Contracting Officer check as appropriate.] ___ (1) 52.222-41, Service Contract Act of 1965 (Nov 2007) (41 U.S.C. 351, et seq.). ___ (2) 52.222-42, Statement of Equivalent Rates for Federal Hires (May 1989) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.). ___ (3) 52.222-43, Fair Labor Standards Act and Service Contract Act -- Price Adjustment (Multiple Year and Option Contracts) (Nov 2006) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.). ___ (4) 52.222-44, Fair Labor Standards Act and Service Contract Act -- Price Adjustment (Feb 2002) (29 U.S.C. 206 and 41 U.S.C. 351, et seq.). ___ (5) 52.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (Nov 2007) (41 U.S.C. 351, et seq.). ___ (6) 52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services--Requirements (Feb 2009) (41 U.S.C. 351, et seq.). ___ (7) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (Mar 2009) (Pub. L. 110-247). ___ (8) 52.237-11, Accepting and Dispensing of \$1 Coin (Sep 2008) (31 U.S.C. 5112(p)(1)). (d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records -- Negotiation. (1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract. (2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR Subpart 4.7, Contractor Records Retention, of the other clauses of this Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved. (3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law. (e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c) and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in paragraphs (e)(1) of this paragraph in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Dec 2008) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 251 note)). (ii) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$550,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities. (iii) 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Section 1553 of Pub. L. 111-5). Applies to subcontracts funded under the Act. (iv) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246). (v) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	and Other Eligible Veterans (Sep 2006) (38 U.S.C. 4212). (vi) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793). (vii) 52.222-39, Notification of Employee rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201). (viii) 52.222-41, Service Contract Act of 1965, (Nov 2007), flow down required for all subcontracts subject to the Service Contract Act of 1965 (41 U.S.C. 351, et seq.) (ix) 52.222-50, Combating Trafficking in Persons (Feb 2009) (22 U.S.C. 7104(g)). ____ Alternate I (Aug 2007) of 52.222-50 (22 U.S.C. 7104(g)). (x) 52.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements (Nov 2007) (41 U.S.C. 351, et seq.) (xi) 52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services--Requirements (Feb 2009) (41 U.S.C. 351, et seq.) (xii) 52.222-54, Employment Eligibility Verification (Jan 2009). (xiii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (Mar 2009) (Pub. L. 110-247). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6. (xiv) 52.247-64, Preference for Privately-Owned U.S. Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64. (2) While not required, the contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations. (End of Clause) Alternate I (Feb 2000). As prescribed in 12.301(b)(4), delete paragraph (d) from the basic clause, redesignate paragraph (e) as paragraph (d), and revise the reference to ?paragraphs (a), (b), (c), or (d) of this clause? in the redesignated paragraph (d) to read ?paragraphs (a), (b), and (c) of this clause. Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Alternate II (Mar 2009). As prescribed in 12.301(b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs (d)(1) and (e)(1) of the basic clause as follows: (d) (1) The Comptroller General of the United States, an appropriate Inspector General appointed under section 3 or 8G of the Inspector General Act of 1978 (5 U.S.C. App.), or an authorized representative of either of the foregoing officials shall have access to and right to? (i) Examine any of the Contractor's or any subcontractors' records that pertain to, and involve transactions relating to, this contract; and (ii) Interview any officer or employee regarding such transactions. (e) (1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), and (c), of this clause, the Contractor is not required to flow down any FAR clause in a subcontract for commercial items, other than? (i) Paragraph (d) of this clause. This paragraph flows down to all subcontracts, except the authority of the Inspector General under paragraph (d)(1)(ii) does not flow down; and (ii) Those clauses listed in this paragraph (e)(1). Unless otherwise indicated below, the extent of the flow down shall be as required by the clause? (A) 52.203-13, Contractor Code of Business Ethics and Conduct (Dec 2008) (Pub. L. 110-252, Title VI, Chapter 1 (41 U.S.C. 251 note)). (B) 52.219-8, Utilization of Small Business Concerns (May 2004) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$550,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities. (C) 52.222-26, Equal Opportunity (Mar 2007) (E.O. 11246). (D) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, Continued ...				

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AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	and Other Eligible Veterans (Sept 2006) (38 U.S.C. 4212). (E) 52.222-36, Affirmative Action for Workers with Disabilities (June 1998) (29 U.S.C. 793). (F) 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004) (E.O. 13201). (G) 52.222-41, Service Contract Act of 1965 (Nov 2007) (41 U.S.C. 351, et seq.). (H) 52.222-50, Combating Trafficking in Persons (Feb 2009) (22 U.S.C. 7104(g)). (I) 2.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (Nov 2007) (41 U.S.C. 351, et seq.). (J) 52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services-Requirements (Feb 2009) (41 U.S.C. 351, et seq.). (K) 52.222-54, Employment Eligibility Verification (Jan 2009). (L) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations. (Mar 2009) (Pub. L. 110?247). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6. (M) 52.247?64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64. Invoice Submission The Contractor shall submit an original invoice and three copies to the address below to receive invoices. Office of Financial Services 12345 Parklawn Drive HFA-720 ROCKVILLE MD 20857 An invoice must include- Name and address of the Contractor; Invoice date and number; Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

AMA ANALYTICAL SERVICES, INC. 286421

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Contract number, contract line item number and, if applicable, the order number; Description, quantity, unit of measure, unit price and extended price of the items delivered; Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading; Terms of any discount for prompt payment offered; Name and address of official to whom payment is to be sent; Name, title, and phone number of person to notify in event of defective invoice; and Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract. Electronic funds transfer (EFT) banking information. The Contractor shall include EFT banking information on the invoice only if required elsewhere in this contract. If EFT banking information is not required to be on the invoice, in order for the invoice to be a proper invoice, the Contractor shall have submitted correct EFT banking information in accordance with the applicable solicitation provision, contract clause (e.g., 52.232-33, Payment by Electronic Funds Transfer-Central Contractor Registration, or 52.232-34, Payment by Electronic Funds Transfer-Other Than Central Contractor Registration), or applicable agency procedures. POC John Gasper 301-436-1133 Laboratory survey of approximately 78 talc-containing products in triplicate to determine asbestiform materials about 234 analyses. The contractor provide the services Continued ...				

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NAME OF OFFEROR OR CONTRACTOR

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ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	indicated under data pack 3 and will provide electron micrographs of fibrous components found in samples, along with x-ray diffraction patterns and/or energy dispersive x-ray analysis spectra used to identify asbestos minerals. The period of performance shall commence from the period beginning contract award through twelve (12) months thereafter. The total amount of award: \$98,748.00. The obligation for this award is shown in box 26.				

AUG 24 2012

quinn emanuel trial lawyers | new york

51 Madison Avenue, 22nd Floor, New York, New York 10010 | TEL 212-849-7000 FAX 212-849-7100

WRITER'S DIRECT DIAL NO.
(212) 849-7316

WRITER'S INTERNET ADDRESS
elizabethbfisher@quinnemanuel.com

2012-6180

August 22, 2012

VIA FACSIMILE (301) 827-9267

Commercial ☒
Nonprofit/Media ☐
Other ☐

Food and Drug Administration
Division of Freedom of Information
Office of Shared Services
Office of Public Information and Library Services
12420 Parklawn Drive
ELEM-1029
Rockville, MD 20857

Re: Public Records Request

To Whom it May Concern:

This is a request under the Freedom of Information Act, pursuant to 5 U.S.C. § 552 *et seq.* I ask that a copy of the documents described in more detail below be provided to me.

I am requesting all documents related to the 2009-2010 analysis of cosmetic talc conducted by AMA Analytical Services, Inc., of Lanham, Maryland (AMA).

According to your website, AMA was retained to test cosmetic talc products for the U.S. Food and Drug Administration from September 28, 2009 to September 27, 2010. *See* <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184>. My request seeks FDA's entire file for this project, including, but not limited to the following categories of documents:

- Protocols, guidance documents and instructions;
- Draft and final results for each sample analyzed;

quinn emanuel urquhart & sullivan, llp

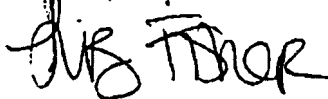
LOS ANGELES | 865 South Figueroa Street, 10th Floor, Los Angeles, California 90017 | TEL 213-443-3000 FAX 213-443-3100
SAN FRANCISCO | 50 California Street, 22nd Floor, San Francisco, California 94111 | TEL 415-875-6600 FAX 415-875-6700
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CHICAGO | 500 West Madison Street, Suite 2450, Chicago, Illinois 60661 | TEL 312-705-7400 FAX 312-705-7401
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TOKYO | NBF Hibiya Bldg., 25F, 1-1-7 Uchisaiwai-cho, Chiyoda-ku, Tokyo 100-0011, Japan | TEL +81 (0) 3 5510-1711 FAX +81 (0) 3 5510-1712
MANNHEIM | Urzbergerstraße 5, 68165 Mannheim, Germany | TEL +49 (0) 621 43298-6000 FAX +49 (0) 621 43298-6100

CFSAN

- Bench sheets, count sheets and any other supporting data created by AMA during the analysis of individual samples;
- Draft and final memorandum, summaries or reports related to this project, whether drafted by AMA or the FDA;
- Any key necessary to determine the source, brand and other identifying characteristics for each sample analyzed;
- Any photographs, scans or printouts relevant to the analysis and project;
- Any documents relevant to the bidding and selection of AMA for this project, including the categories referenced on your website which notes that AMA was selected "to conduct this laboratory survey, based on demonstrated experience with asbestos analysis in complex matrices, appropriate facilities, equipment, personnel, analytical strategy, and budget criteria";
- Correspondence between FDA and AMA relevant to this project; and
- Correspondence between FDA and/or AMA and any manufacturer, supplier or distributor regarding the acquisition of samples, testing or results.

Please do not hesitate to call me at (212) 849-7316 regarding the logistics and fees for obtaining the materials requested or regarding any questions related to my request. Thank you for your attention to this matter.

Sincerely,



Elizabeth Fisher

QUINN EMANUEL URQUHART & SULLIVAN, LLP

LOS ANGELES

865 South Figueroa Street, 10th Floor
Los Angeles, CA 90017-2543
(213) 443-3000
Facsimile: (213) 443-3100

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San Francisco, CA 94111-4788
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Facsimile: (415) 875-8700

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(312) 705-7400
Facsimile: (312) 705-7401

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1299 Pennsylvania Avenue NW
Suite 825
Washington, DC 20004-2400
(202) 538-8000
Facsimile: (202) 538-8100

NEW YORK OFFICE FACSIMILE TRANSMISSION

DATE: August 22, 2012

NUMBER OF PAGES, INCLUDING COVER: 3

NAME/COMPANY	PHONE NO.	FAX NO.
Food and Drug Administration Division of Freedom of Information Office of Shared Services Office of Public Information and Library Services		(301) 827-9267

FROM: Elizabeth Fisher
(212) 849-7316
elizabethfisher@quinnemanuel.com

RE: Public Records Request

CLIENT # 61821

ROUTE/
RETURN TO: E. Fisher
☐ CONFIRM FAX
☐ INCLUDE CONF. REPORT

OPERATOR:

CONFIRMED? ☐ NO ☐ YES:

The information contained in this facsimile is confidential and may also contain privileged attorney-client information or work product. The information is intended only for the use of the individual or entity to whom it is addressed. If you are not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this communication is strictly prohibited. If you have received the facsimile in error, please immediately notify us by telephone, and return the original message to us at the address above via the U.S. Postal Service. Thank you.

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Elizabeth Fisher
Quinn Emanuel Urquhart & Sullivan
51 Madison Avenue
22nd Floor
New York, NY 10010-

In reply refer to:
2012-6180

Dear Ms. Fisher:

This is in reply to your Freedom of Information request dated August 22, 2012 for all documents related to the 2009-2010 analysis of cosmetic talc conducted by AMA Analytical Services, Inc., Lanham, Maryland.

Food and Drug Administration regulations at 21 CFR § 20.45 (d)(2) provides that if the agency's initial review of an FOIA request indicates that charges will exceed \$250.00, the requester will be required to pay the estimated fees before the search for the requested records begins.

The Center for Food Safety and Applied Nutrition (CFSAN) will provide its responsive records for a total charge of \$1,113.00. The total charges include estimated reproduction charges of \$8.00 for 80 pages at \$.10 per page, \$1,104.00 for 24 hours of review time at \$46.00 per hour, and \$1 for a CD Rom. For more information on FDA's FOIA processing fees, please see the following website:
<http://www.fda.gov/RegulatoryInformation/FOI/FOIFees/default.htm>.

If you wish to receive the information please submit payment in the amount of \$1,113.00 by check or money order, **with the above FOI file number made payable to Food and Drug Administration** and mail with a copy of this letter to:

- a. **Via the US Mail** -
US Food & Drug Administration
P.O. Box 979107
St. Louis, MO 63197-9000
- b. **Via Courier Delivery**, to:
Government Lockbox 979107
1005 Convention Plaza
St. Louis, MO 63101

NOTE: the Courier address is for payment only, and the Lockbox number must appear on the enclosed check.

So, that we may begin processing your request as soon as possible, please fax a copy of this letter and a copy of your check or money order to my attention at 301-436-2668. Please note: if payment is not received by October 12, 2012 your request will be closed.

As the above charges are estimated charges, the final amount may be more or less than this estimated amount; if they are less you will be refunded the difference; if more, you will receive an invoice for the difference.

Sincerely,

Patricia Gee
FOI Officer
Executive Operations Staff
Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

QUINN EMANUEL URQUHART & SULLIVAN, LLPLOS ANGELES

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FACSIMILE TRANSMISSION****DATE:** November 29, 2012**NUMBER OF PAGES, INCLUDING COVER: 4**

NAME/COMPANY	PHONE NO.	FAX NO.
Attn: Patricia Gee Food and Drug Administration		301-436-2668

FROM: Melissa Forquer**RE: FOIA
REQUEST
2012-6180****MESSAGE:**

CLIENT # 61821

ROUTE/
RETURN TO: Melissa Forquer☐ CONFIRM FAX
☐ INCLUDE CONF. REPORT

OPERATOR:

CONFIRMED? ☐ NO ☐ YES:

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QUINN EMANUEL URQUHART & SULLIVAN, LLP

424317

VENDOR NO. 7257

VENDOR NAME: FOOD AND DRUG ADMINISTRATION

CHECK DATE: 11/29/12

REFERENCE NUMBER	INVOICE DATE	G/L ACCOUNT	DESCRIPTION	NET AMOUNT PAID
2012-6180	09-21-12	101001200000000000000000	#61821/RESPONSE TO FOIA REQUEST 9/21/12	1,113.00
TOTAL				\$1,113.00

QUINN EMANUEL URQUHART & SULLIVAN, LLP

424317

DATE: 11/29/12

AMOUNT: \$1,113.00****

PAY ONE THOUSAND ONE HUNDRED THIRTEEN AND 00/100 Dollars

TO THE
ORDER
OF

FOOD AND DRUG ADMINISTRATION
P.O. BOX 979107
ST. LOUIS, MO 63197-9000

Non-Negotiable



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 21 2012

Food and Drug Administration
Rockville MD 20857

Elizabeth Fisher
Quinn Emanuel Urquhart & Sullivan
51 Madison Avenue
22nd Floor
New York, NY 10010-

In reply refer to:
2012-6180

Dear Ms. Fisher:

This is in reply to your Freedom of Information request dated August 22, 2012 for all documents related to the 2009-2010 analysis of cosmetic talc conducted by AMA Analytical Services, Inc., Lanham, Maryland.

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Page 2 - Ms. Fisher

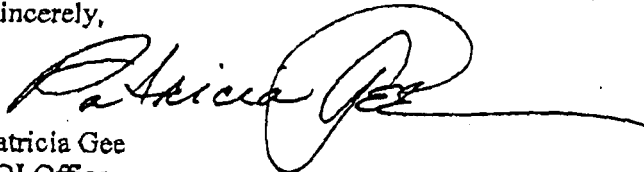
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Patricia Gee
FOI Officer
Executive Operations Staff
Food and Drug Administration
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5100 Paint Branch Parkway
College Park, MD 20740-3835



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 21 2012

Food and Drug Administration
Rockville MD 20857

Elizabeth Fisher
Quinn Emanuel Urquhart & Sullivan
51 Madison Avenue
22nd Floor
New York, NY 10010-

In reply refer to:
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Page 2 – Ms. Fisher

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