August 13, 2021

Via Email

Accelerated Device Approval Services, LLC
Rafael Aguila
President
65 NW 48th Place
Miami, FL 33126

RE: Request for a Hearing under 21 CFR Part 16 regarding the Notice of Intent to Withdraw Accreditation and Notice of Opportunity for Hearing

Dear Mr. Aguila,

This letter responds to your March 26, 2021 hearing request submitted by Accelerated Device Approval Services, LLC (ADAS or you). ADAS requests a hearing under 21 CFR part 16 on the Center for Devices and Radiological Health's (CDRH's) proposal to withdraw the accreditation of ADAS in FDA's Third Party 510(k) (3P510k) Review Program. CDRH's proposal to withdraw accreditation is based on findings that ADAS is substantially not in compliance with section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and has failed to act in a manner that is consistent with the purposes of section 523.

As Chief Scientist, I have the authority to perform all the delegable functions of the Commissioner of Food and Drugs (Commissioner).[1] Based on my review of your hearing request and the administrative record, I find that there is no genuine and substantial issue of fact as to whether ADAS is substantially not in compliance with section 523 of the FD&C Act or has failed to act in a manner that is consistent with the purposes of that section. Therefore, I am denying ADAS's request for a hearing and finalizing CDRH's proposal to withdraw ADAS's accreditation under section 523(b)(2)(B) of the FD&C Act.

Procedural Background

Section 523 of the FD&C Act authorizes the 3P510k Review Program. Under this authority, CDRH accredits third parties, known as "3P510k Review Organizations," to review 510(k) submissions and recommend the initial classification of certain eligible devices. Under the 3P510k Review Program, a 3P510k Review Organization reviews a company's 510(k) submission, makes a recommendation regarding whether the device is substantially equivalent (SE) or not substantially equivalent (NSE) to a legally marketed device, and submits the 510(k)

[1] FDA SMG 1410.21, "General Redelegations of Authority from the Commissioner to Other Officers of the Food and Drug Administration," at 1.B.6.

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notification on the sponsor's behalf to CDRH for further regulatory review, along with a memo supporting the 3P510k Review Organization's recommendation. CDRH then has 30 days to review the memo and recommendation and make a final decision about whether to clear the device or devices in the sponsor's 510(k) submission.[2]

On June 28, 2018, ADAS applied to CDRH for accreditation under section 523 of the FD&C Act. ADAS's application included a flow chart outlining its proposed 510(k) review process, which would include "assignment to a Product Specialist, selection of a Technical Expert (if necessary), and final review and submission to CDRH by a Final Reviewer."[3] ADAS's application also included a list of personnel who would be involved in the 3P510k review process:[4]

Job Position	Name of the person
Owner and President of ADAS	Ana Reifschneider
Product Specialist	Rafael Aguila
Final Reviewer	Konrad Kobel

ADAS provided curriculum vitae (CV) for its product specialist and, importantly, for its final reviewer, Konrad Kobel.[5] Konrad Kobel's CV named him as the former "Vice-President of QM/RA" of Aesculap AG and listed over 30 years of experience in the medical device industry.[6] On August 20, 2018, based on the information contained in ADAS's submission, CDRH accredited ADAS to perform third party 510(k) reviews.[7]

On March 12, 2021, CDRH proposed withdrawing ADAS's accreditation in FDA's 3P510k Review Program. CDRH supported its proposal with numerous exhibits, including documents ADAS submitted to FDA, emails between ADAS and its client or FDA, and a signed declaration from Konrad Kobel.[8]

CDRH based its proposal on two grounds. First, CDRH determined that ADAS had made false representations with respect to Kobel in its application for accreditation and had falsely represented through a forged signature that Kobel served as ADAS's lead reviewer for subsequent 510(k) submissions:

> ADAS' 2018 accreditation materials made false representations about the identity, qualifications, and signatures of its final reviewer, whom ADAS identified as Konrad Kobel, and included a false [CV] for Mr. Kobel. Moreover, in thirty-one

[2] *See* section 523(a)(2)(B) of the FD&C Act (21 USC 360m(a)(2)(B)).
[3] CDRH's Memo: Intent to Withdraw Accreditation of ADAS in the 3P510k Review Program (CDRH Memo) at 4.
[4] *See id.* at 4 (citing Notice of Opportunity for Hearing (NOOH) Ref. 7, Appendix H).
[5] *See* NOOH Ref. 7, Appendix G.
[6] *See id*.
[7] *See* NOOH Ref. 5.
[8] *See* CDRH Memo.

> 510(k) review submissions to CDRH, ADAS falsely identified Konrad Kobel as its product specialist and/or its final reviewer and forged Mr. Kobel's signature. In fact, Konrad Kobel has never been employed by ADAS or performed a 3P510K review for ADAS, the CV submitted with ADAS' accreditation application was altered to falsely show Mr. Kobel's employment at ADAS, and Konrad Kobel did not sign any of the ADAS documents bearing his name and purported signature.[9]

Second, CDRH found that "ADAS made false and misleading representations to its client, Cryptych, by telling Cryptych that CDRH had requested additional information regarding Cryptych's NuroChek 510(k) [submission] and that CDRH suggested that Cryptych withdraw that 510(k) [submission] when, in fact, ADAS had not yet submitted Cryptych's NuroChek 510(k) to CDRH."[10] CDRH found specifically, based on its review of emails:

> [O]n August 7, 2019, ADAS conveyed to Cryptych what it claimed was an additional information request from CDRH, and on February 6, 2020, ADAS told Cryptych that "the [CDRH] reviewer believes that you should withdraw the current 510(k) [submission], and resolve the two problems before filing a new 510(k) [notification]." But ADAS did not submit the 510(k) [notification] for Cryptych's NuroChek device[,] and ADAS' recommendation regarding such 510(k) [notification] to CDRH until March 19, 2020. CDRH did not make the "additional information request" or the suggestion that Cryptych withdraw its NuroChek 510(k) [notification] that ADAS conveyed to Cryptych.[11]

On March 26, 2021, ADAS submitted its request for a hearing on the findings contained in CDRH's proposal to withdraw accreditation. On April 15, 2021, CDRH submitted a response to ADAS's request for hearing and requested that ADAS's request for a hearing be denied. On April 27, 2021, ADAS submitted a reply to CDRH's response to ADAS's hearing request.

Analysis

Under section 523(b)(2)(B) of the FD&C Act, FDA may withdraw accreditation of any accredited third party when the third party (1) is substantially not in compliance with the requirements of section 523; (2) poses a threat to public health; or (3) fails to act in a manner that is consistent with the purposes of section 523. Section 523 lists many minimum requirements for accredited persons, including operating "in accordance with generally accepted professional and ethical business practices."[12]

Although "generally accepted professional and ethical business practices" is not defined, the International Medical Device Regulators Forum (IMDRF) has written criteria for reviewer competence, training, and conduct and for organizations that perform regulatory audits and other functions. The "510(k) Third Party Review Program: Guidance for Industry, Food and Drug

[9] NOOH at 2.
[10] *Id.* at 3.
[11] *Id.* at 3.
[12] Section 523(b)(3)(E) of the FD&C Act (21 USC 360m(b)(3(E)).

Administration Staff, and Third Party Review Organizations" encourages third party reviewers to refer to IMDRF criteria, and states that third party reviewers in compliance with the IMDRF criteria "are likely to be in compliance with most FDA 3P510k Review Organization requirements."[13] The IMDRF has emphasized that professional/ethical business practices include a commitment "[t]o record and report truthfully and accurately review assessments performed in an impartial and unbiased way" and "to record and report truthfully and accurately any material facts that may affect the regulatory review process."[14]

Under 21 CFR 16.26(a), the Commissioner may deny a request for a hearing, in whole or in part, if the Commissioner, or the Commissioner's delegate who has authority to make the final decision on the matter, finds that the materials submitted do not raise a genuine and substantial issue of fact. The standard for denial of a hearing under 21 CFR 16.26(a) aligns with the standard in federal court for summary judgment. *See John D. Copanos & Sons, Inc. v. Food & Drug Admin.*, 854 F.2d 510, 523 (D.C. Cir. 1988) (stating that principles for summary judgment under Federal Rules of Civil Procedure "apply with equal force in context of administrative judgment"). A genuine and substantial issue of fact must be material – that is, one that would affect the outcome of the proceeding. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *see also Hess & Clark, Div. of Rhodia, Inc. v. Food & Drug Admin.*, 495 F.2d 975, 983 (D.C. Cir. 1974) (while discussing an FDA order withdrawing approval of a new animal drug application, the D.C. Circuit stated, "When the FDA issues a Notice of Opportunity for Hearing, its summary judgment procedures are available if the requesting party fails to raise material issues of fact."). Moreover, a party opposing summary judgment "may not rest upon mere allegation or denials of his pleading, but must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 256.

For the reasons discussed below, I find that ADAS's hearing request does not create a genuine and substantial issue of fact for a hearing. ADAS has not presented any arguments or evidence that raises a material dispute with respect to the critical factual questions at issue in this matter, specifically, whether ADAS was substantially not in compliance with the requirements of section 523 of the FD&C Act or failed to act in a manner that is consistent with the purposes of section 523.

In its request for a hearing, ADAS submits a list of 38 questions that "ADAS will ask during the requested informal meeting."[15] Many questions focus on Konrad Kobel's purported signature (specifically, why FDA believes that ADAS knew about the "supposed deception"), how FDA intends to prove that ADAS forged the signature, whether FDA can confirm that FDA personnel did not tamper with the "true and correct signature of Konrad Kobel," and why Kobel's declaration was not notarized.[16] ADAS also includes questions on whether other third-party review organizations submitted information about ADAS to FDA and what evidence FDA has to suggest that "ADAS falsely misrepresented" various information to Cryptych.[17] Finally, ADAS

[13] *See* "510(k) Third Party Review Program: Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations" at 35, available at https://www.fda.gov/media/85284/download.
[14] *See* NOOH Ref. 6 at 8.
[15] *See* ADAS Request for Hearing at 1-6.
[16] *See* ADAS Request for Hearing at 1-3.
[17] *See* ADAS Request for Hearing at 3.

presents questions related to its pending re-recognition application and includes accusations of inappropriate behavior by CDRH employees.[18]

In addition to these questions, ADAS makes a variety of assertions related to the signature purporting to be Kobel's in ADAS's submissions to FDA, ADAS's interactions with Cryptych, and "potential malevolent motivations of [CDRH employee] (b) (6) against ADAS."[19] ADAS's subsequent reply reiterates many of these same arguments.

1. False Representations regarding Konrad Kobel and Forgery of his Signature

CDRH first maintains that ADAS was substantially not in compliance with the requirements of section 523 and failed to act in a manner that is consistent with the purposes of section 523 when it falsely represented to CDRH that Konrad Kobel was an ADAS employee.

CDRH states that that it identified an individual named Konrad Kobel who appeared to have similar experience to the "Konrad Kobel" whose CV ADAS submitted. According to CDRH, during a March 11, 2020 phone call, it discussed with Kobel his role in the 3P510k Review Program, and Kobel stated that he had not worked as a third-party reviewer in that program.[20] CDRH stated that Kobel confirmed that the CV submitted by ADAS for "Konrad Kobel" aligned with his own previous experience, including his previous employment at Aesculap AG.[21] Through Kobel, CDRH also identified a 510(k) submission by Aesculap AG that purported to bear Kobel's signature. CDRH states that the signature on Aesculap AG's submission differs from the one contained in ADAS's third-party review memorandum and other ADAS submissions containing a signature purporting to be that of a "Konrad Kobel."[22] On March 20, 2020, Kobel provided CDRH with a written statement confirming that he has never been part of CDRH's 3P510k Review Program and that the signature submitted by ADAS, which was provided to him, was not his signature.[23] Kobel stated, in part, "I have never been employed by ADAS. I did not write this CV and I did not give ADAS, or anyone else, permission to use my name or to modify my CV to represent to FDA that I worked as a 'Final Reviewer' at ADAS."[24]

In its hearing request, ADAS states that it had no reason to believe that the "Konrad Kobel" who had been a reviewer for ADAS was falsely misrepresenting his identity.[25] ADAS asserts that FDA provided no "concrete evidence" that the "Kobel" working at ADAS was not who he said he was, in part because the declaration provided by FDA was not notarized.[26] ADAS states that, after it received the proposal to withdraw accreditation, ADAS asked its employee "Konrad

[18] *See* ADAS Request for Hearing at 3-6. Insofar ADAS submits information relating to a separate request for re-recognition of ADAS in the 3P510k Review Program, this re-recognition request is not relevant to the notice of intent to withdraw accreditation, so I will not address these arguments in this decision.
[19] *See* ADAS Request for Hearing at 7-10.
[20] *See* CDRH Memo at 7; Ref. 8; Ref. 12.
[21] *See* CDRH Memo at 7.
[22] *See* NOOH Ref. 9 at 4, 5.
[23] *See* NOOH Ref. 8; Ref. 12.
[24] NOOH Ref. 12 at 3.
[25] *See* ADAS Request for Hearing at 7.
[26] *See id.* at 7.

Kobel" to confirm his identity, and he did to ADAS's satisfaction.[27] ADAS claims that "Konrad Kobel" declined to provide any evidence to confirm his identity because he was "offended," but he has since been replaced as the final reviewer.[28]

ADAS's response does not present sufficient evidence to warrant a factual hearing concerning whether its submissions to CDRH signed by "Konrad Kobel" are not a basis for withdrawing accreditation. Mere denials are not enough to raise a genuine and substantial issue of fact.

It is a mystery as to what the ADAS employee claiming to be "Konrad Kobel" did to confirm his identity to ADAS, as ADAS has not offered any facts to support that confirmation. CDRH's response to your request for a hearing correctly points out that if another man named "Konrad Kobel" exists and worked for ADAS, ADAS could have produced other records to confirm that person's identity, such as pay stubs or tax forms.[29] The "Konrad Kobel" whose work history appears to be described in the CV submitted by ADAS, provided a statement to CDRH that he did not work for ADAS or in the 3P510k Review Program.[30] Whether the declaration is notarized is not dispositive; rather, ADAS has failed to offer any evidence or fact-based explanation to address the case laid out in CDRH's proposal as it relates to Konrad Kobel. CDRH also presented evidence of Kobel's signature from another submission, which does not match the signature on submissions from ADAS purporting to be from "Konrad Kobel." ADAS again presents no factual evidence addressing the differing signatures presented by CDRH; therefore, ADAS has not created a genuine and substantial issue of fact regarding CDRH's allegations pertaining to Konrad Kobel's signature.

ADAS's statement that the "Konrad Kobel" in its employ no longer works there is not relevant to whether ADAS submitted numerous documents to FDA that falsely represented a particular individual as working for ADAS. Further, even if ADAS was unaware of an employee's misrepresentation, ADAS had an obligation to verify the identity of one of its employees—in this case, its Final Reviewer—before submitting any documentation to FDA regarding that employee or pertaining to his work. ADAS's failure to verify the identity of its Final Reviewer demonstrates unprofessional conduct, violates IMDRF guidelines, and is harmful to the 3P510k Review Program.

Instead of presenting any arguments or support that may raise a factual dispute about this allegation, ADAS merely tries to redirect the focus to CDRH. However, doing so does not create a genuine material dispute of fact for a hearing. Indeed, as discussed above, there is no genuine and substantial issue of fact with respect to whether ADAS submitted documents containing misrepresentations regarding Kobel's employment with ADAS, including forged signatures on 31 submissions to CDRH. Such conduct undermines the integrity of the 3P510k Review Program. Falsifying employee information and forging signatures on submissions is unprofessional and unethical business conduct; therefore, ADAS is substantially not in compliance with the requirements of section 523 of the FD&C Act. I therefore find that ADAS has failed to justify a hearing on as to whether ADAS is substantially not in compliance with the

[27] *See id.* at 7.
[28] *See id.* at 7-8.
[29] *See* CDRH Response to ADAS Request for Hearing at 10.
[30] *See* CDRH Memo at 7; Ref. 12.

requirements of section 523 for falsely representing that Konrad Kobel was an ADAS employee and forging his signature, and ADAS failed to act in a manner that is consistent with the purposes of section 523 by falsely representing to CDRH that Konrad Kobel was an ADAS employee and forging his signature.

2. False and Misleading Statements to Cryptych

CDRH next contends that ADAS is substantially not in compliance with the requirements of section 523 of the FD&C Act and failed to act in a manner that is consistent with the purposes of section 523 when it made false and misleading representations to Cryptych with respect to the status of a 510(k) submission. Specifically, CDRH maintains that ADAS falsely informed or suggested to Cryptych that ADAS had completed its review of Cryptych's 510(k) notification for a device, NuroChek, and submitted its findings to FDA when, in fact, it had not. CDRH also alleges that ADAS falsely conveyed that CDRH made additional information requests of Cryptych.

In support of its position, CDRH points to several email chains between Cryptych and ADAS.[31] In one of the email chains, dated November 20, 2019, ADAS informed Cryptech that, "we will provide [] the FDA with our decision [on the 510(k) submission for NuroCheck]. Within 30 days, the FDA will review our decision and issue a final approval."[32] Cryptech emailed on December 11, 2019 asking ADAS whether there was any feedback from FDA regarding its 510(k) submission for NuroChek.[33] On December 13, 2019, ADAS responded and stated, "We have no news yet from the FDA. However, we will let you know as soon as we have more to tell you."[34] On December 23, 2019, Cryptech followed up again with ADAS, and ADAS stated that it "spoke with the FDA reviewer in charge of your 510(k) application" and stated that FDA did not agree with the number of people included in the submission for usability testing.[35] On January 8, 2020, ADAS again reiterated via email that "the FDA reviewer" wanted to see more participants in the usability testing.[36] Further, on January 10, 2020, ADAS increased the number that the "FDA reviewer . . . would like to see" for the usability testing.[37] On February 4, 2020, after submitting additional information, Cryptych asked ADAS to "confirm that the FDA has received the report and if there has been any feedback to date."[38] On February 6, 2020, ADAS told Cryptych that it spoke with the reviewer who looked at the revised information and described two issues that "prevents them[39] from granting a 510(k) clearance" for the device.[40] At the end of that same email, ADAS stated that, "the reviewer believes that you should withdraw the current 510(k) application, and resolve the two problems before filing a new

[31] *See* NOOH Ref. 2; Ref 3.
[32] NOOH Ref. 2.
[33] *Id.*
[34] *Id.*
[35] *See id.*
[36] *See id.*
[37] *See id.*
[38] NOOH Ref. 3.
[39] As noted in the previous sentence, Cryptych asked if FDA received the report and had any feedback. ADAS responded with the above language, making the use of "them" appear to be referencing "the FDA" from the previous email in this exchange.
[40] NOOH Ref. 3.

510(k)."[41] It is undisputed, however, that ADAS did not submit a 510(k) package to FDA regarding NuroChek until March 19, 2020.[42]

ADAS states that it is untrue that it had "falsely stated that CDRH had made Additional Information requests [regarding the usability testing] or that CDRH recommended that Cryptych withdraw its 510(k) application."[43] ADAS claims that FDA provides "no direct evidence" of these statements and further states that, even though ADAS "would constantly try to correct Cryptych and its employees about the Third-Party Review process and the fact that ADAS´ reviewers were not part of CDRH," there was a "misunderstanding" by Cryptych that ADAS's final reviewer was the FDA reviewer.[44] ADAS asserts that "Cryptych would describe all our reviewers as 'FDA reviewers' during telephone conversations. Accordingly, to avoid confusion, we would state that ADAS's 'FDA Reviewer' had additional information requests."[45] ADAS explained that it provided the option to Cryptych to withdraw its 510(k) submission instead of receiving an NSE. ADAS states that, "it is common for the reviewers who work directly with CDRH to provide this option to 510(k) sponsors (i.e. withdraw or receive an NSE)."[46] ADAS also states that the delay in issuing the proposal to withdraw "shows that FDA was not concerned with this issue until now."[47] In ADAS's later reply, ADAS makes numerous statements related to "Cryptych's behavior" and its device that are separate from the issues identified in the NOOH.[48]

ADAS's claims that it did not make false or misleading statements to Cryptych and that the noted concerns arise from Cryptych's misunderstanding are belied by a simple review of emails between Cryptych and ADAS. In one email Cryptych pointedly asked about the status of its application with FDA, and ADAS stated that there was no news from FDA, even though it had not yet submitted Cryptych's application to FDA for it to receive any kind of response.[49] In another instance, ADAS recommended that Cryptych withdraw its 510(k) submission, without explaining that the submission was pending with ADAS, as opposed to CDRH.[50] These were just two examples of false or misleading statements made from ADAS to Cryptych. ADAS does not contest these facts except to suggest that Cryptych misunderstood ADAS's meaning.

Even if those statements were not false, they were clearly misleading. ADAS had numerous opportunities to clarify with Cryptych who was reviewing its 510(k) submission and when

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[41] *Id.*
[42] *See* NOOH Ref. 11.
[43] ADAS Request for Hearing at 10.
[44] *See also* ADAS Reply to CDRH's Response at 16 (stating "During many of the teleconferences with Cryptych, they would constantly refer to ADAS as being part of the FDA. But this was based on Cryptych´s own misunderstandings about the 510(k) Third Party Review process, not because ADAS tried to confuse Cryptych. ADAS and its representatives would constantly try to correct Cryptych and its employees about the Third-Party Review process and the fact that ADAS´s reviewers were not part of CDRH. Instead, ADAS was accredited by CDRH to conduct Third-Party Reviews of 510(k) application and then provide CDRH with a Review Memo and recommendation.").
[45] ADAS Request for Hearing at 10.
[46] *Id.*
[47] *Id.*
[48] *See* ADAS Reply to CDRH's Response at 6-8.
[49] *See* NOOH Ref. 2.
[50] *See* NOOH Ref. 3.

ADAS would actually submit it to FDA. CDRH's response to the hearing request identifies numerous places where ADAS did not correct Cryptych's understanding of the status of its 510(k) submission or clarify Cryptych's "misunderstanding" relating to the 510(k) submission.[51] One such instance is the discussion related to the number of participants in the usability study. ADAS told Cryptych that it had "spoke[n] with the FDA reviewer in charge of your 510(k) application. They said that the FDA does not agree tha (b) (4) people is enough for the usability testing."[52] As noted in CDRH's response to your request for a hearing, "Cryptych later asked that ADAS let them 'know where the FDA' was in its review and for a "follow up on the[] FDA feedback."[53] ADAS did not correct Cryptych or clarify that there had been a misunderstanding as to who was requesting the usability data, despite having numerous opportunities to do so. ADAS's lack of clarification throughout its review process provides no reassurance that it is meeting the professional business standards outlined in the IMDRF.[54]

Separately, ADAS's statements related to Cryptych and its device are irrelevant to the issue at hand, which is ADAS's actions as a third-party reviewer. ADAS's contention that CDRH's failure to issue its proposal to withdraw sooner are also not relevant. CDRH's timelines for issuing decisions or proposed regulatory actions are not at issue in this proposal.

Whether ADAS's conduct in misleading Cryptych concerning the status of its submission was deliberate is immaterial to whether the uncontested facts related to these communications show that ADAS was substantially not in compliance with the requirements of section 523 of the FD&C Act and failed to act in a manner that is consistent with the purposes of section 523. Based upon the emails forwarded to FDA, Cryptych was in fact misled about the status of its 510(k) submission. Additionally, even if ADAS did not intend to mislead ADAS, ADAS failed to meet the basic requirements of professional business standards by not ensuring that their client understood something as simple as whether its 510(k) submission was being reviewed by ADAS or FDA. ADAS's conduct, specifically making misleading statements to Cryptych, fails to meet generally accepted professional and ethical business practices and makes ADAS substantially not compliance with the requirements of section 523. ADAS offered no tangible evidence that created a material factual dispute over CDRH's claims. The uncontested evidence shows that ADAS failed to act in a manner consistent with the purposes of section 523. As a result, I find that ADAS has not raised any genuine and substantial issues of fact that would merit a hearing relating to the Cryptych allegations; therefore, I deny ADAS a hearing on these allegations.

3. ADAS's Secondary Arguments

In addition to responding to CDRH's main allegations in the proposal to withdraw, ADAS makes additional arguments related to a specific CDRH employee, (b) (6), as well as statements related to CDRH's allegations under the law in the District of Columbia. ADAS states that it is "important to know the motivation behind (b) (6) investigation" given that (b) (6) already verified the information in ADAS's initial application to become a

[51] *See* CDRH Response to ADAS Request for Hearing at 9.
[52] *See* NOOH Ref. 2.
[53] CDRH Response to ADAS Request for Hearing at 9.
[54] ADAS's mere allegation that it tried to correct Cryptych's misunderstanding of the third-party review process is not sufficient to raise a genuine and substantial issue of fact for a hearing. *Cf. Anderson*, 477 U.S. at 256.

third-party reviewer.[55] ADAS accuses (b) (6), a CDRH employee, of inappropriate conduct. ADAS claims that Mr. (b) (6) is not an "independent party to investigate ADAS in a neutral manner" and that ADAS's previous accusations of sexism and racism against Mr. (b) (6) are why he began his investigation into ADAS. Separately, ADAS states that, "at a trial," FDA would not be able to establish all the elements of fraudulent misrepresentation under DC law.[56]

ADAS's allegations relating to Mr. (b) (6) provide no legitimate grounds for a hearing. ADAS submitted exhibits that it claims relate to Mr. (b) (6) "malevolent motivations" against the company.[57] None of these allegations relate to the central issues in the proposal to withdraw accreditation, and, as discussed above, ADAS has failed to present any genuine and substantial issues of fact in this matter.

Further, ADAS's arguments relating to DC law are immaterial because the proceeding hinges on whether ADAS's conduct justifies withdrawing accreditation under section 523 of the FD&C Act, not whether its conduct violated DC law.

Conclusion

Based on the uncontested facts in the record, and for the reasons described above, under 21 CFR 16.26, I find that there is no genuine and substantial issue of fact regarding whether there are grounds to justify the withdrawal of ADAS's accreditation under section 523 of the FD&C Act. Pursuant to section 523(b)(2)(B), I am withdrawing ADAS's accreditation from the 3P510k Review Program.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.08.13 13:27:39 -04'00'

RADM Denise M. Hinton
Chief Scientist

Cc: Robert L. Pfeferman, Esq., Counsel for Accelerated Device Approval Services, LLC
Seth I. Heller, Associate Chief Counsel, FDA, Counsel for CDRH

[55] *See* ADAS Request for Hearing at 7.
[56] *See id.* at 9.
[57] *See id.* at 9; Ex. 3; Ex. 4; Ex. 7.