NOTICE OF INTENT TO WITHDRAW ACCREDITATION
NOTICE OF OPPORTUNITY FOR HEARING

VIA EMAIL

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

March 12, 2021

Dear Mr. Aguila:

This letter is to inform you that, pursuant to section 523(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Center for Devices and Radiological Health (CDRH) intends to withdraw the accreditation of Accelerated Device Approval Services, LLC (ADAS) in FDA's Third Party 510(k) (3P510k) Review Program, because ADAS is substantially not in compliance with section 523 of the FD&C Act and has failed to act in a manner that is consistent with the purposes of section 523.[1] Specifically, as explained below and in more detail in the attached memorandum, after reviewing ADAS' June 28, 2018 accreditation application, ADAS' submissions to CDRH under the 3P510k Review Program, and other available information, CDRH has concluded that ADAS made numerous false representations to CDRH regarding the identity, qualifications, and competency of personnel conducting its 510(k) reviews and made false and misleading representations about CDRH's regulatory communications to one of its clients, Cryptych Pty Ltd (Cryptych). Each of these activities independently justifies withdrawal of ADAS' accreditation under section 523(b)(2)(B) of the FD&C Act, for two independent reasons: ADAS is substantially not in compliance with section 523 of the FD&C Act, and ADAS fails to act in a manner that is consistent with the purposes of section 523.

Pursuant to section 523(b)(2)(B) of the FD&C Act, CDRH 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. Although section 523 contains numerous requirements, it expressly lists minimum requirements an accredited person must meet, including operating "in accordance with generally accepted professional and ethical business practices." *See* section 523(b)(3)(E). Pursuant to section 523(b)(2)(B) of the FD&C Act, CDRH is providing ADAS with notice and the opportunity for an informal hearing under 21 CFR part 16. The instructions for requesting a hearing under 21 CFR part 16 are provided at the end of this letter. ADAS has the right to be advised and represented by counsel at all times. Any regulatory hearing on this matter will be governed by the regulations in 21 CFR parts 16 (regulatory hearing before the Food and Drug Administration (FDA)) and 10, subpart C (guidelines on electronic media coverage of administrative proceedings). Enclosed you will find copies of these regulations. Below, we briefly describe the evidence supporting withdrawal of ADAS's accreditation; the attached memorandum discusses such evidence in greater detail. These are the issues that would be considered at the regulatory hearing, if granted.

[1] Without accreditation, ADAS will not be permitted to review 510(k) submissions and make recommendations to CDRH regarding the initial classification of devices under section 513(f)(1) of the FD&C Act.

False Representations Regarding the Identity, Qualifications, and Competency of ADAS Personnel

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 curriculum vitae (CV) for Mr. Kobel. Moreover, in thirty-one 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.[2] 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.

ADAS is substantially not in compliance with the requirements of section 523 for falsely representing that Konrad Kobel was an ADAS employee

Section 523(b)(3) of the FD&C Act requires that an accredited person meet a number of requirements, including that it conduct its operations "in accordance with generally accepted professional and ethical business practices." *See* section 523(b)(3)(E). 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 (IMDRF Report).[3] The IMDRF Report sets an objective standard in this specific area of business for professional and ethical business practices.

The IMDRF Report establishes a code of conduct for individuals who perform regulatory reviews of medical devices for marketing authorization. In particular, the IMDRF Report emphasizes 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." (IMDRF Report at 8). Furthermore, in its 2018 accreditation application, ADAS established a code of conduct for itself, including the requirement that all ADAS employees "act in a professional and ethical manner at all times," "not to act in any way prejudicial to the interest or reputation of FDA," and "record and report truthfully any material fact that may affect the reliability of [ADAS' 3p510(k)] review."

ADAS has failed to meet both the IMDRF's and its own standards of professional and ethical business practice. ADAS' 2018 accreditation application made false representations about the identity, qualifications, and signatures of its final reviewer and ADAS has falsely represented to CDRH that Mr. Kobel reviewed thirty-one 510(k) submissions it made to CDRH. Falsifying employees' identities, qualifications, and competencies, and forging signatures on submissions to CDRH is neither professional nor ethical business conduct,[4] and therefore, ADAS is substantially not in compliance with the requirements of section 523. For that reason alone, ADAS' accreditation should be withdrawn.

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

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[2] CDRH notes that each of ADAS' thirty-one recommendations includes a certification attesting to truth and accuracy of the representations made therein and notes that the submission of false information to the government is prohibited by federal law.

[3] The IMDRF Report is available at: Competence, Training, and Conduct Requirements for Regulatory Reviewers (imdrf.org).

[4] Indeed, section 301(y)(1) of the FD&C Act prohibits "the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect."

Section 523 and the 3P510k Review Program are intended to provide certain device manufacturers with a way to get their lower-risk products cleared for marketing by FDA more rapidly and to permit FDA to focus its resources on higher-risk and complex devices by relying on third party reviews for lower-risk devices. *See* 63 FR 28388 (May 22, 1988). It is critical that 510(k) sponsors have confidence in the accredited third-party reviewers and that CDRH can trust third parties to be truthful and ethical.

Submitting an application for accreditation that falsely represented that Konrad Kobel was an ADAS employee, altering Mr. Kobel's CV, and forging Mr. Kobel's signature in the accreditation application and in thirty-one submissions to CDRH, undermines the integrity of the third-party program and is inconsistent with the purposes of section 523.

In sum, ADAS' false representations to CDRH about Mr. Kobel's role in its company and review process provide two separate and independent legal bases for withdrawing ADAS' accreditation: ADAS is substantially not in compliance with the requirements of section 523, and ADAS fails to act in a manner that is consistent with the purposes of section 523. As described below, ADAS engaged in further conduct that provides additional independent support for withdrawing its accreditation.

False and Misleading Representations to Cryptych

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) and that CDRH suggested that Cryptych withdraw that 510(k) when, in fact, ADAS had not yet submitted Cryptych's NuroChek 510(k) to CDRH. Specifically, emails reviewed by CDRH show that on 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) application, and resolve the two problems before filing a new 510(k)." But ADAS did not submit the 510(k) for Cryptych's NuroChek device and ADAS' recommendation regarding such 510(k) to CDRH until March 19, 2020. CDRH did not make the "additional information request" or the suggestion that Cryptych withdraw its NuroChek510(k) that ADAS conveyed to Cryptych.

ADAS is substantially not in compliance with the requirements of section 523 for making false and misleading representations to Cryptych

ADAS lied to and misled Cryptych regarding CDRH's review of the NuroChek 510(k). Such conduct fails to meet generally accepted professional and ethical business practices (see discussion above regarding the IMDRF Report and ADAS' code of conduct). Accordingly, ADAS is substantially not in compliance with the requirements of section 523 based on its false and misleading representations to Cryptych.

ADAS failed to act in a manner that is consistent with the purposes of section 523 by making false and misleading representations to Cryptych

As discussed above, section 523 is intended to support CDRH's mission to protect and promote public health by enabling CDRH to focus its internal scientific review resources on higher-risk and complex devices, while maintaining a high degree of confidence in the review of low-to-moderate risk and less complex devices by 3P510k Review Organizations. To accomplish these purposes, CDRH must trust third parties like ADAS to be truthful and ethical.

ADAS' false and misleading representations to its client Cryptych regarding CDRH's review of Cryptych's NuroChek 510(k) undermine the integrity of the third party review process and are inconsistent with the purposes of section 523.

In sum, ADAS' false and misleading representations to Cryptych provide two additional, separate, and independent legal bases for withdrawing ADAS' accreditation: ADAS is substantially not in compliance with the requirements of section 523, and ADAS fails to act in a manner that is consistent with the purposes of section 523.

Conclusion

CDRH has determined that ADAS is substantially not in compliance with section 523 of the FD&C Act and has failed to act in a manner that is consistent with the purposes of that section. Therefore, for the reasons described above and in more detail in the attached memorandum, CDRH is providing you notice of its intent to withdraw ADAS' accreditation in accordance with section 523(b)(3)(B) of the FD&C Act.

ADAS is entitled to an opportunity for an informal hearing concerning withdrawal of its accreditation.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that warrants a hearing. Pursuant to 21 CFR 16.26, a request for a hearing may be denied, in whole or in part, if the Commissioner or the Commissioner's delegee determines that no genuine and substantial issue of fact has been raised by the material submitted. A hearing will not be granted on issues of policy or law. Written notice of a determination of summary judgment will be provided, explaining the reasons for denial of the hearing.

Your request for an informal hearing must be submitted to FDA in writing no later than fourteen (14) calendar days after the date of this letter. If no response is received by FDA within this time, the offer is deemed to have been refused and no hearing will be held (see 21 CFR 16.22(b)). Your request for a hearing should be directed to:

CDRH-Ombudsman
Center for Devices and Radiological Health
U.S. Food and Drug Administration
E-mail address: CDRHOmbudsman@fda.hhs.gov
cc: Matthew.Warren@fda.hhs.gov

Alternatively, if you do not desire a hearing but wish to submit a written response, you may respond in writing within 14 calendar days of the date of this letter. Your response should include any information that you believe would affect FDA's decision to withdraw ADAS' accreditation as a 3P510k Review Organization in the 3P510k Review Program. FDA will make its final decision regarding withdrawal of your accreditation on the bases explained in this letter, any written response from you, and other information available to FDA. Please be aware that this notice letter and any response to this notice letter may be posted on FDA's website, with redactions for any confidential information.

If you have any questions regarding this letter, please contact Robert A. Sauer, Division Director, Division of Program Operations and Management, phone: 301-796-3580 and email: Robert.A.Sauer@fda.hhs.gov.

Sincerely yours,

Timothy T. Stenzel -S

Timothy Stenzel, M.D., Ph.D.
Director
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosures:

1. Copy of 21 CFR part 16
2. Copy of 21 CFR part 10, subpart C
3. Memorandum and References