HARD COPY

ADMINISTRATIVE PROCEEDING

File No. 3-17293

In the Matter of

Advanced Life Sciences Holdings, Inc., *et al.*,

Respondents.

ADVANCED LIFE SCIENCES' PETITION FOR REVIEW OF AN INITIAL DECISION TO THE DIVISION OF ENFORCEMENT'S MOTION FOR SUMMARY DISPOSITION.

Michael T. Flavin, Ph.D. (630) 991-3013
mflavin@advancedlifesciences.com
Chief Executive Officer
Advanced Life Sciences Holdings, Inc.
1440 Davey Road
Woodridge, IL 60517

We have received the Initial Decision Release No. 1065 Administrative Proceeding File No. 3-17293 from the U.S. Securities and Exchange Commission regarding Advanced Life Sciences Holdings, Inc. and dated October 12, 2016.

The purpose of this document is to file a petition for review of this Initial Decision made by Administrative Law Judge Grimes.

Advanced Life Sciences Holdings, Inc. ("ADLS") is a Delaware corporation located in Woodridge, IL and is a biopharmaceutical company focused on the discovery, development and commercialization of novel drugs in the area of infectious disease.

We have been developing our antibiotic cethromycin through clinical trials for the treatment of a variety of dangerous infections such as pneumonia, especially those caused by pathogenic bacteria that are resistant to other antibiotics. There is a great need for new antibiotics given the increasingly rapid emergence of drug-resistant pathogens here in the United States and around the globe.

In late 2008, we completed our Phase 3 clinical trials of cethromycin against pneumonia and, in 2009, we submitted our New Drug Application (NDA) to the FDA for their review. Later that year, the FDA convened an advisory committee meeting of expert infectious disease physicians to review our NDA and provide recommendations regarding the safety and efficacy of cethromycin to the agency. The advisory committee voted overwhelming in favor of the safety of the drug. However, with regard to drug efficacy,

the advisory committee asked us to go back and redo clinical trials according to guidelines the FDA had put in place even after our clinical trials had been completed. Thus, even though we met the efficacy goals of the Phase 3 clinical trials we had designed and agreed to with the FDA in 2005, we were asked to design and carry out new trials under the new FDA guidelines.

Because of this setback, our stock price plummeted into penny stock range in 2009. Although we worked diligently to design a new clinical trial that would meet the new FDA guidelines, it took us almost a year to reach agreement with the FDA on what the specifications would be for the new clinical trial. As we reached the end of 2010, it became extremely difficult to raise additional capital to continue to fund our clinical program.

In late April, 2011, because of our lack of liquidity, we were forced to put the Company into suspension. Up until that time, beginning in August, 2005, ADLS filed every quarterly and annual report on time. Since April, 2011, the Company's executive team worked with attorneys at the law firms of Polsinelli, PC and Perkins Coie, LLP along with Certified Public Accountant professionals from Miller Cooper & Co. to prepare a comprehensive 10K document covering the years 2011 through 2015, which was submitted to Suzanne Hayes of the Division of Corporate Finance at the SEC on July 27, 2016. The comprehensive 10K document that we filed with the SEC on July 27, 2016 describes the events leading up to the Company's suspension of operations and during the time period that elapsed until December, 2015. This comprehensive 10K

document provides useful information to the Company's shareholders, updating them on all events since the last SEC filing in December, 2010.

The ADLS Board of Directors has been and remains in regular communication and has designed a plan for moving ADLS forward. In addition, we have been in communication with the FDA and have met with agency representatives to learn what ADLS will need to do to receive approval for cethromycin.

We respectfully request that the SEC allow ADLS to maintain our registration status in order for Company shareholders to realize value in their investment and provide ADLS the opportunity to raise the additional capital required to carry out the clinical trials that the FDA has asked us to conduct in order to achieve regulatory approval and commercialization of what can be a life-saving antibiotic. We would greatly appreciate the opportunity to help make that happen.