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United States Sentencing Commission
One Columbus Circle, NE
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Attention: Public Affairs

Re: Comments to Federal Register Notice, Vol. 73, No. 18, published Monday, January 28, 2008, at pages 4931-4939; Notice of Proposed Amendments to Sentencing Guidelines.

Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the United States Sentencing Commission is considering promulgating certain amendments to the sentencing guidelines, policy statements, and commentary. This notice sets forth the proposed amendments, a synopsis of each amendment, and various issues for comment. Written public comment regarding the proposed amendments and issues for comment set forth in this notice, including public comment regarding retroactive application of any of the proposed amendments, should be received by the Commission not later than March 28, 2008. (73 FR 4931-4939)

To Whom it May Concern:

On behalf of our client Air Liquide USA LLC (Air Liquide), we submit the following comments. Air Liquide appreciates the opportunity to comment on the aforementioned proposed amendments to the Sentencing Guidelines.

Air Liquide is a leading manufacturer and supplier of medical, industrial and specialty gases with manufacturing facilities in over 70 countries and U.S. corporate headquarters in Houston, Texas.

As a manufacturer and supplier of medical gases that are regulated by the U.S. Food and Drug Administration (FDA), the company has an interest in the proposed amendments to the sentencing guidelines and submits the following comments for consideration:

First, Air Liquide supports the comments as submitted by attorneys John R. Fleder and John A. Gilbert of Hyman, Phelps & McNamara, P.C., who participated in the panel testifying before the Commission regarding the proposed Guideline changes concerning

the Federal Food, Drug, and Cosmetic Act (FDC Act) and the Prescription Drug Marketing Act (PDMA) violations. Both attorneys testified on February 13, 2008 with respect to § 2N2.1 of the proposed amended guidelines, titled "Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product." According to the Commission's proposal issued in the Federal Register:

> Both Mr. Fleder and Mr. Gilbert took the position in their testimony that § 2N2.1 appears to be working as intended and that there is insufficient evidence that the § 2N2.1 Guideline needs to be revised at this time.

Second, Air Liquide is concerned that if the proposed amended Guidelines are adopted, the change would almost certainly dramatically increase sentences to be imposed in cases where "loss" is at issue (probably in all felony cases). Under the present standard of "current good manufacturing practices", the extent of compliance is meant to evolve over time. Consequently, products that are manufactured in compliance with "current" GMPs today can be out of compliance at a future date. Moreover, the non-compliant products (which were in compliance in the past) would not need to be reprocessed, retested or otherwise revised in order to be used safely and effectively, thereby meeting the health care community's or the consumers' expectations on both a therapeutic and economic level. Yet, the proposed amendments' change in how the term "loss" is defined would appear to cause all products that are out of compliance with cGMPs to be deemed valueless. Such a radical change in defining "loss" raises serious legal and policy issues that the Commission should investigate before adopting.

Additionally, the term "current good manufacturing practice" is not defined by the FDC Act itself. Instead, the law allows FDA to publish regulations to define its requirements and expectations in this area. FDA's regulations describe the minimum requirements for conforming to cGMPs in general rather than specific terms. FDA issues Guidance documents to provide specifics, but the Guidances are not legally binding.[1] Furthermore, FDA's cGMP requirements evolve over time as noted above. For example, FDA's first Guidance on compressed medical gases was issued in June 1981 and revised in 1983. In February 1989, FDA issued another revision of the Guidance, which was updated again in "draft" form in May 2003. See Guidance for Industry, Current Good Manufacturing

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[1] FDA Guidance documents contain the following or a similarly-worded caveat: "This draft guidance, when finalized, will represent the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

Practice for Medical Gases (Draft, May 2003), at p. 1. Because they are meant to cover a wide range of product types, the regulations use subjective terms such as adequate, appropriate, sufficient, etc., the meaning or application of which often results in disputes, which FDA recognizes.[2] In our view, the proposed amendments could lead to the imposition of increased sentences even in cases where the cGMP compliance violation represents a relatively "new" interpretation by an FDA investigator.

Third, Air Liquide believes FDA's position in support of the amendments is unrealistic in its scope and could lead to extended sentencing terms for minor infractions. For instance, an FDA-regulated product is deemed misbranded if the product was manufactured at a registered facility, but the particular product was not properly listed. Similarly, many FDA-regulated products are deemed adulterated if they have been manufactured outside the very general cGMP requirements, even if the cGMP deficiency cited by a particular FDA investigator involved an issue such as a record-keeping mistake that does not affect the inherent identity, strength, quality or purity of the product.

Given the multi-national, multi-faceted and multi-sited traits of many FDA-regulated companies that will be governed by the Sentencing Guidelines, it is imperative that the Commission ensure that any amendment to the specific language, general policies or commentary of the Sentencing Guidelines preserve the present balance between real-world common sense and strict liability for corporate officers.

In conclusion, Air Liquide would like to thank the Commission for its consideration of these comments and would like to reinforce that current guidelines are sufficient and believe the amendments should be disallowed.

Sincerely,

Gary L. Yingling

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[2] "Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with cGMP requirements or during the Agency's assessment of corrective actions undertaken as a result of such inspections. As these disputes may involve complex judgments and issues that are scientifically or technologically important, it is critical to have procedures in place that will encourage open, prompt discussion of disputes and lead to their resolution." Guidance for Industry, Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP (January 2006), at p. 1.