ORAL ARGUMENT NOT YET SCHEDULED

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN FARM BUREAU FEDERATION, *et al.* Petitioners, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	Docket No. 06-1410 (and consolidated cases)

On Petitions for Review of Final Actions
of the United States Environmental Protection Agency

BRIEF OF INTERVENORS AMERICAN LUNG ASSOCIATION AND ENVIRONMENTAL DEFENSE

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Dated: January 29, 2008

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with Circuit Rule 28(a)(1), Intervenors American Lung Association and Environmental Defense submit this certificate as to parties, rulings, and related cases.

(A) Parties, Intervenors and *Amici* in case 06-1410 and consolidated cases

All parties, intervenors, and *amici* appearing in this court are listed in the Petitioners' briefs.

(B) Circuit Rule 26.1 Disclosure for Intervenors

American Lung Association. American Lung Association has no parent companies, and no publicly held company has a 10 percent or greater ownership interest in the American Lung Association.

American Lung Association, a corporation organized and existing under the laws of the State of Maine, is a national nonprofit organization dedicated to the conquest of lung disease and the promotion of lung health.

Environmental Defense. Environmental Defense has no parent companies, and no publicly held company has a 10 percent or greater ownership interest in Environmental Defense.

Environmental Defense, a corporation organized and existing under the laws of the State of New York, is a national nonprofit environmental organization

dedicated to creating innovative, equitable and cost-effective solutions for the most urgent environmental problems.

(C) Rulings Under Review

The agency actions under review are "National Ambient Air Quality Standards for Particulate Matter; Final Rule," 71 Fed. Reg. 61144 (Oct. 17, 2006), and "Revisions to Ambient Air Monitoring Regulations; Final Rule," 71 Fed. Reg. 61236 (Oct. 17, 2006).

(D) Related Cases

Other than the petitions for review consolidated with this action, American Lung Association and Environmental Defense are not aware of any related cases.

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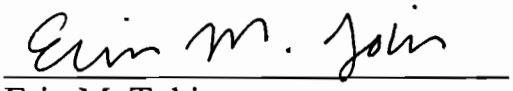
DATED: January 29, 2008

Respectfully submitted,



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GLOSSARY

Act	The federal Clean Air Act, 42 U.S.C. §§ 7410, *et seq.*
ALA	American Lung Association
CASAC	Clean Air Scientific Advisory Committee
EPA	United States Environmental Protection Agency
μm	Micrometers. Used as a measure of particle diameter.
$\mu g/m^3$	Micrograms per cubic meter. A measure of the concentration of a substance in a volume of air.
NAAQS	National Ambient Air Quality Standards
$PM_{2.5}$	Particulate matter having a nominal aerodynamic diameter of 2.5 micrometers or smaller. Also referred to as fine particulate matter.
PM_{10}	Particulate matter having a nominal aerodynamic diameter that is less than or equal to 10 micrometers.
$PM_{10-2.5}$	Particulate matter having a nominal aerodynamic diameter that is between 2.5 and 10 micrometers. Also referred to as coarse particulate matter.

STATUTES

Pertinent statutes appear in the Petitioners' Addenda.

STATEMENT OF THE ISSUE

Whether EPA complied with the Clean Air Act by issuing a national ambient air quality standard for all coarse particulate matter that is consistent with record evidence of risk to public health.

STATEMENT OF FACTS

A. Statutory Framework

The Clean Air Act ("CAA" or "Act") sets up a process for establishing national ambient air quality standards ("NAAQS") for pollutants that may endanger public health. 42 U.S.C. §§ 7408(a)(1), 7409(b)(1). EPA must review these standards every five years. *Id.* § 7409(d)(1). The Clean Air Scientific Advisory Committee ("CASAC") also reviews the NAAQS and makes recommendations to the Administrator. *Id.* § 7409(d)(2)(A), (B).

B. EPA's Regulation of Coarse Particulate Matter

Particulate matter ("PM") refers to a broad class of physically diverse substances that exist as discrete particles. 52 Fed. Reg. 24634, 24635 (July 1, 1987). In 1987, EPA concluded that particles smaller than or equal to 10 μm in diameter ("PM_{10}") can penetrate the thoracic region of the respiratory system, and in doing so present "markedly greater" risks to human health than larger particles.

Id. at 24639. Accordingly, EPA established a 24-hour primary PM_{10} standard of 150 μg/m^3 that provides a "margin of safety below the levels at which there is a scientific consensus that particulate matter causes premature mortality and aggravation of bronchitis." *Id.* at 24643.

In 1997, EPA determined that a "greatly expanded body of health effects information" demonstrated that the 24-hour PM_{10} standard was not protecting the public from adverse health effects, including mortality, exacerbation of chronic disease, increased hospital admissions, increased respiratory symptoms, school absences, and lung function decrements. 62 Fed. Reg. 38652, 38655, 38657 (July 18, 1997). EPA added a new indicator for "fine" PM (particles less than or equal to 2.5 μm in diameter, or "$PM_{2.5}$"). *Id.* at 38655.

On January 13, 2006, EPA proposed replacing the 24-hour PM_{10} standard with a "coarse" PM standard (*i.e.*, covering particles between 2.5 and 10 μm in diameter) that excluded any mix of coarse PM "dominated" by PM from agriculture and mining sources. 71 Fed. Reg. 2620, 2674 (Jan. 17, 2006). In determining whether the coarse PM standard is met, EPA also proposed to use only data from monitors in any "urbanized" area with a population of at least 100,000 and a density of 500 or more persons per square mile. *Id.* at 2782. EPA proposed setting the 24-hour coarse PM standard at 70 ug/m^3.

CASAC objected to EPA's proposal to exempt agricultural and mining sources from the coarse PM NAAQS, and to not protect the public in non-"urban" areas. Letter from Dr. Rogene Henderson, Chair, CASAC, to Stephen Johnson, Administrator, EPA, 4 (Mar. 21, 2006) [JA___]. Members of the public also strenuously opposed the proposed exemptions for agriculture and mining sources and rural areas. *See*, *e.g.*, Comments of the American Lung Association, *et al*. (April 17, 2006) ("ALA Comments") [JA__]. On October 17, 2006, EPA decided to abandon the proposed exemptions, and instead to retain a 24-hour standard for PM_{10}. 71 Fed. Reg. 61144, 61192-93 (Oct. 17, 2006) (rejecting an urban-only coarse PM indicator because of the importance of protecting the public from "all thoracic coarse particles").

SUMMARY OF THE ARGUMENT

American Farm Bureau Federation, *et al.* ("Industry Petitioners") challenge EPA's decision to retain a 24-hour standard for PM_{10}. Industry Petitioners contend that EPA lacks authority to set a standard for coarse particles in rural areas. Industry Petitioners also argue that a uniform national standard results in unnecessary protection in rural areas, in violation of the Act's requirement that NAAQS must be "requisite" to protect public health. Both arguments are premised on the faulty claim that the record does not demonstrate health risks from particulates outside "urban" areas.

As detailed below, there is ample support in the record for retaining a NAAQS that regulates coarse PM regardless of geographic origin or pollution source. In light of its finding that all particles less than 10 μm endanger public health, EPA was not required to make additional findings of endangerment for subsets of coarse PM emitted by Industry Petitioners. Industry Petitioners' desire for a standard that excludes whole rural areas and source categories would run counter to the evidence in the record, the recommendations of scientists, and the precautionary purpose of the CAA.

ARGUMENT

I. EPA Reasonably Retained PM_{10} as a Criteria Pollutant Under CAA Section 108.

Industry Petitioners incorrectly contend that EPA is required to make a threshold showing of "real and significant risk" from rural coarse PM before establishing a PM_{10} NAAQS. Brief of American Farm Bureau, *et al.* ("Indust. Br.") at 16. Simply put, the CAA does not mandate that EPA make a threshold finding of "significant" health risks before establishing NAAQS. Nor is EPA required to make separate endangerment findings for subsets of coarse PM emitted in different areas or by different sources.

The threshold finding Industry Petitioners appear to invoke is the finding EPA must make when it lists a pollutant under section 108 of the Act. That section directs EPA to identify "criteria" pollutants that are ubiquitous in the ambient air

"the emissions of which . . . cause or contribute to air pollution which *may reasonably be anticipated to endanger public health or welfare*." 42 U.S.C. § 7408(a)(1) (emphasis added).

Nothing in the Act precludes the listing of a pollutant until the Administrator makes a definitive demonstration of "significant" harm. Rather, by referring to emissions that "may" be anticipated to endanger public heath, the statute clearly requires that EPA list a pollutant when it is merely *possible* that the pollutant endangers public heath. *See* Webster's New World Dictionary (2d ed. 1982) (defining "may" to mean "possibility or likelihood"). The terms "anticipate" and "endanger" further reflect Congress' intent to emphasize EPA's "duty to assess risks *rather than wait for proof of actual harm*." H.R. Rep. 95-294, at 51 (1977), *reprinted in* U.S. Code Cong. & Admin. News 1077, 1129 (emphasis added).

Industry Petitioners never address this statutory language, instead attempting to invent a higher threshold through case law that has little relevance to section 108. They rely on *Whitman v. American Trucking Ass'ns*, in which the Supreme Court compared the requirements for setting NAAQS under the CAA to the requirements for setting workplace safety standards under the Occupational Safety and Health Act, as evidence that the CAA requires a finding of "significant risk" before EPA can establish NAAQS. Indust. Br. at 16. However, the *Whitman* Court only compared these statutes for purposes of determining whether the CAA

amounts to an unconstitutional delegation of authority, not to suggest that the Act requires a finding of "significant" harm. *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 473 (2001).

Industry Petitioners also mischaracterize dicta in *Alabama Power Co. v. Costle* as suggesting that EPA has no discretion to regulate rural coarse PM not expressly found to present a "substantial risk to public health." Indust. Br. at 15-7. To the contrary, the cited footnote explains that EPA has the "*discretion* to define the pollutant termed 'particulate matter' to exclude particulates of a size or composition determined not to present substantial public health or welfare concerns." *Alabama Power Co. v. Costle,* 636 F.2d 323, 370 n.134 (D.C. Cir. 1979) (emphasis added). The *Alabama Power* court clearly understood that EPA has discretion to exclude from regulation some particulates it has affirmatively determined do not present "substantial" health and welfare concerns, and to include particulates when EPA has *not* made such a determination.

Thus, the Act and its legislative history are plain that the threshold for listing a criteria pollutant is low and intended to be precautionary. Moreover, section II.B. demonstrates that there is ample record support for retaining PM_{10} as a criteria pollutant under section 108, and for retaining the primary 24-hour PM_{10} standard under section 109.

II. EPA Reasonably Included All PM_{10} in the NAAQS Under CAA Section 109.

Industry Petitioners additionally contend that setting a national standard for PM_{10} violates section 109's requirement that NAAQS must be "requisite" to protect public health, because the record does not demonstrate a need to regulate coarse PM in rural areas. Indust. Br. at 25. However, Industry Petitioners have ignored section 109's precautionary standard and the more than sufficient record evidence that non-urban coarse PM endangers public health.

A. Section 109 Demands That EPA Err on the Side of Caution When There is Uncertainty.

Section 109 directs EPA to establish NAAQS for listed pollutants "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." 42 U.S.C § 7409(b)(1). In arguing that EPA failed to comply with section 109, Industry Petitioners grasp at language in *Whitman* construing "requisite" to mean "sufficient, but not more than necessary" to protect public health. Indust. Br. at 22-3. Industry Petitioners not only ignore the fact that *Whitman* did not involve a challenge to the appropriate level of a NAAQS, but they also ignore critical language in the Court's definition of "requisite" – *i.e.*, that NAAQS must first be "sufficient" to protect public health. *Whitman*, 531 U.S. at 473.

This Court has long recognized the inherent limitations of scientific knowledge in identifying a precise safe level of pollution. *See, e.g., Lead Indust. Ass'n v. EPA*, 647 F.2d 1130, 1156 n.50 (D.C. Cir. 1980) (the CAA "reflect[s] awareness of the uncertainties and limitations in the data [because] decisionmaking about the risks to public health from air pollution falls on the frontiers of scientific and medical knowledge") (internal quotations omitted). This Court explicitly found that section 109's requirement of "requisite" public health standards demands that EPA act in the face of this inevitable uncertainty – *i.e.*, *before* EPA "conclusively demonstrate[s] that a particular effect is adverse to health." 647 F.2d at 1155. In keeping with the Act's precautionary directive, the NAAQS must "*ensure* that there is an '*absence* of adverse effects'" from exposure to listed pollutants. *Id.* at 1153 (emphasis added). Nothing in *Whitman* affects the precautionary principle driving the setting of NAAQS under section 109.

Industry Petitioners also fail to address language in section 109 directing the Administrator to set standards that provide an "adequate margin of safety" to protect public health. 42 U.S.C § 7409(b)(1). As this Court has explained, this language requires that EPA set standards to protect against health effects "which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement." *Lead Indust.*, 647 F.2d at 1154. In so doing, EPA need not regulate only the known dangers to health, but should "'err' on the side of

overprotection by setting a fully adequate margin of safety." *American Petroleum Inst. v. Costle*, 665 F.2d 1176, 1187 (D.C. Cir. 1981).

The CAA is clear that Congress intended EPA to err on the side of caution: when there is uncertainty as to health effects from listed pollutants, and EPA cannot "ensure" an "absence" of such effects, EPA must set standards to protect public health. *Lead Indust.*, 647 F.2d at 1153. As demonstrated in section II.B., a national standard for coarse PM is justified because there is substantial record evidence that all particles smaller than 10 μm endanger public health. There is *no* evidence that excluding rural coarse PM would "ensure" an absence of health effects. Accordingly, Industry Petitioners' claim that EPA must exclude these particles from the PM_{10} standard must fail.

B. There is Ample Evidence Supporting a NAAQS For All Particles Smaller Than or Equal to 10 μm in Diameter.

In claiming that the PM_{10} standard is not supported by the record, Indust. Br. at 17-22 and 23-6, Industry Petitioners ignore the overwhelming scientific evidence showing that coarse particles endanger public health regardless of their source or geographic origin. Since 1987, EPA has consistently found that exposure to particles less than 10 μm in diameter is of concern, not because of the composition of those particles *per se*, but because the particles can deposit in the thoracic region of the respiratory system. 71 Fed. Reg. at 61178.

The 1987 PM_{10} standard was based on occupational, toxicological, and epidemiological studies demonstrating a need to regulate coarse PM to protect against health effects such as aggravation of asthma, upper respiratory illness, broncioconstriction, altered clearance, and damage to alveolar tissue. 71 Fed. Reg. at 2654; 52 Fed. Reg. at 24649. To address these health concerns, EPA concluded that a PM indicator should represent "those particles small enough to penetrate to the thoracic region." *Id.* at 24639. Although Industry Petitioners are correct that EPA considered London smog data that measured particles 4.5 micrometers and smaller, EPA also relied on newer epidemiological studies that more reliably estimated PM_{10} levels. *Id.* at 24643.

In 1997, EPA confirmed these findings based on updated data that continued to support that particles smaller than or equal to 10 μm in size are harmful to public health because they can deposit in the thoracic region of the respiratory system. 62 Fed. Reg. at 38666-67. Before vacating the 1997 PM_{10} standard on other grounds, a panel of this Court concluded that there was "ample support" for a standard that regulates coarse PM. *American Trucking Ass'ns v. EPA*, 175 F.3d 1027, 1054 (D.C. Cir. 1999).

In its 2006 review, EPA analyzed more recent studies, many of which address coarse PM. The evidence continues to demonstrate that exposure to coarse particles is associated with death, heart-related and respiratory-related hospital

admissions, decreased lung function growth, and possibly carcinogenic effects. Air Quality Criteria for Particulate Matter (Oct. 2004) ("Criteria Document") 7-171, 8-186, 8-206, 8-303 to 306, 8-309 to 313, 8-337 [JA__]; Review of the National Air Quality Standards for Particulate Matter (Dec. 2005) ("Staff Paper") 3-9, 5-48 to 49 [JA__]. With CASAC's concurrence, EPA concluded that coarse particles "present a risk of adverse effects to the most sensitive regions of the respiratory tract." 71 Fed. Reg. at 61177; Letter from Dr. Rogene Henderson, Chair, CASAC, to Stephen Johnson, Administrator, EPA, at 5 (Sept. 15, 2005) 4[JA__] ("Sept. 2005 CASAC Letter").

Studies that analyze specific sources of PM also consistently show that coarse particles, from all variety of sources, adversely affect human health. Although there is limited data concerning the health effects of rural coarse PM, this is because most studies of coarse PM are from urban areas. This does not mean that the data "shows" that rural coarse PM is "*not* associated with adverse health effects." Indust. Br. at 17 (emphasis in original).

To the contrary, the record includes evidence of health risks from exposure to non-urban dusts, including health effects in farmers exposed to dusts and airborne endotoxins (toxic chemicals associated with bacteria), and fungal infections from exposure to "natural dust storms" and "dust-generating" agricultural activities. Criteria Document 7B-11, 7B-21 to 22, 7B-25, 7B-31 to 32

[JA__]; *see also* ALA Comments 103-108 [JA__] (discussing studies showing risks to agriculture and mining workers and communities near these industries, including respiratory disease, acute and chronic bronchitis, chronic obstructed airways disease, interstitial lung disease, asthma, and organic dust toxic syndrome). More recent studies in the record have found adverse health effects from exposure to coarse PM from volcanic ash and Asian dust storms. *See* 71 Fed. Reg. at 61190.

EPA specifically found that some studies showed health effects from coarse PM in areas "dominated" by crustal particles that typically occur in rural areas. 71 Fed. Reg. at 61190-91. In particular, one study in Coachella Valley found statistically significant associations between coarse particles and death from heart disease, which EPA and CASAC believe are "suggestive" of health effects from exposure to rural coarse PM. *Id.*

More fundamentally, even assuming *arguendo* that particulates are of concern not because of their size but because of their source, any distinction between "urban" and "rural" PM is completely artificial. The same sources of coarse PM exist both in "urban" and "rural" areas, and may be contaminated with the same toxic components. The record thus shows that *all* crustal particles may be contaminated with heavy metals from steel mills, polycyclic aromatic hydrocarbons from automobile exhaust, and pesticides from agricultural activities

and "*become sufficiently toxic to cause health effects*." Criteria Document 8-344 [JA__] (emphasis added). In addition, other well-known toxics prevalent in agricultural and mining industries may contaminate coarse PM in the same manner as do toxics in urban areas, including silica, molds, fungi, pollen, endotoxins, toxic biologic compounds, and inorganic ions. Criteria Document 7-106, 8-338, 9-5, 9-62 to 63, 9-74, 9-80 [JA__]; ALA Comments 94-8 [JA__].

Industry Petitioners point to EPA's discussion of studies petitioners contend "show" that rural coarse PM is benign, including one study that found no evidence of health effects from exposure to dust storms in Spokane, Washington, and toxicology studies that found no evidence of health effects from exposure to Mt. St. Helen's volcanic ash. Indust. Br. at 18-9. Industry Petitioners, however, fail to refute EPA's reason for discounting the Spokane study results: that adverse health effects were absent because people stay indoors on days of high winds or dust. 71 Fed. Reg. at 61190-91. Nor have Industry Petitioners refuted that at least one study found that exposure to dust storms in Spokane *was* associated with hospitalizations for bronchitis and sinusitis. *Id*. The volcanic ash studies have also been contradicted by new evidence, and are unhelpful anyway because "uncontaminated" volcanic ash is not representative of rural coarse PM. *Id*.; ALA Comments 98-9 [JA__]. In any event, these paltry studies do not rebut the significant evidence demonstrating health impacts from a wide range of PM

sources and, hence, do not "ensure" an "absence" of adverse effects. For EPA to exclude rural coarse PM based on these studies, in the face of significant evidence to the contrary, would have been arbitrary and capricious in the extreme.

C. Industry Petitioners Ignore EPA' Rationale for Retaining the 24-Hour PM_{10} Standard Level of 150 $\mu g/m^3$.

In faulting EPA for retaining the PM_{10} standard level of 150 $\mu g/m^3$, Industry Petitioners first assert that even if a standard for non-urban PM is justified, EPA has never demonstrated that a PM_{10} standard level of 150 $\mu g/m^3$ is "requisite" to protect public health from exposure to rural coarse PM. Indust. Br. at 23. This is a strawman argument. EPA also has never demonstrated that the standard is requisite for particles in "suburban" or desert areas, or from fireplaces, older diesel trucks, or sandy soil. Nothing compels this piecemeal standard setting. The record provides ample reason to be concerned with *all* particles 10 μm or smaller. As explained above, it would have been unreasonable for EPA to distinguish between particles based on origin or source when the same sources and contaminants may occur in any area. 71 Fed. Reg. at 61189.

Industry Petitioners argue further that the 150 $\mu g/m^3$ PM_{10} level is not "requisite" for PM_{10} generated in either urban or rural areas because the 1987 standard protected against health effects from both fine and coarse PM, not solely coarse PM, as here. Indust. Br. at 24. Industry Petitioners falsely contend that in retaining the 1987 PM_{10} standard, "EPA is continuing in effect a level that has

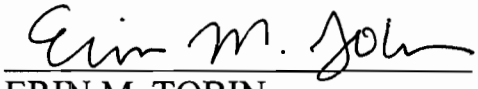
never been evaluated as requisite to protect against exposure to coarse PM." *Id*. As recommended by EPA staff and approved by CASAC, EPA evaluated studies that found health effects from exposure to coarse PM, identified the levels of coarse PM causing such health impacts, and determined whether health impacts from exposure to coarse PM were occurring in areas that attained the existing PM_{10} standard. 71 Fed. Reg. at 61199-61202; Staff Paper 5-63 to 5-67 [JA__]; Sept. 2005 CASAC Letter [JA__]. Although Environmental Intervenors argued that the evidence supported a more protective coarse PM standard, ALA Comments 108-112 [JA___], EPA concluded that existing PM_{10} protections were sufficient because most studies that found health effects from exposure to coarse PM occurred in areas that did not attain the 1987 PM_{10} standard. 71 Fed. Reg. at 61200. Industry Petitioners make no attempt to refute this basis for EPA's determination that a level of 150 $\mu g/m^3$ for coarse PM is requisite to protect public health.

Industry Petitioners also attack EPA's finding in the final rule that the PM_{10} standard provides appropriately targeted protection from coarse particles that is justified by the science, but because Petitioners did not comment on EPA's specific rationale for that finding as stated in the final rule, 71 Fed. Reg. at 61195-97, or raise their objections in a petition for administrative reconsideration, those arguments cannot be raised for the first time here. 42 U.S.C. § 7607(d)(7)(B).

CONCLUSION

For the foregoing reasons, the Court should uphold EPA's decision to retain the 24-hour PM_{10} standard. In light of the significant public health concerns at stake, if the Court agrees with any of Industry Petitioners' arguments, the Court should remand EPA's decision without vacating the 2006 PM_{10} standard. Industry also asks the Court to instruct EPA that the 1987 PM standard is unlawful, but the Court lacks jurisdiction to hear such an untimely request. 42 U.S.C. § 7607(b)(1) (60-day limitation on challenges to EPA action).

DATED: January 29, 2008.



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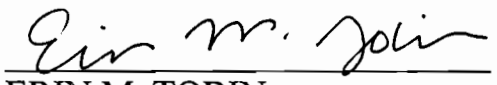
CERTIFICATE OF COMPLIANCE WITH WORD LIMITATION

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I hereby certify that the foregoing brief is within the applicable word limit set in the Court's July, 31, 2007 order, in that it contains 3,500 words according to counsel's word processing system.

DATED: January 29, 2008



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CERTIFICATE OF SERVICE

I hereby certify that on January 29, 2008, the foregoing **BRIEF OF INTERVENORS AMERICAN LUNG ASSOCIATION AND ENVIRONMENTAL DEFENSE** was served by United States first-class mail, (or, where an email address is set forth, electronically pursuant to written consent obtained under Fed. R. App. P.25(c)(1)(D)), upon the following:

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