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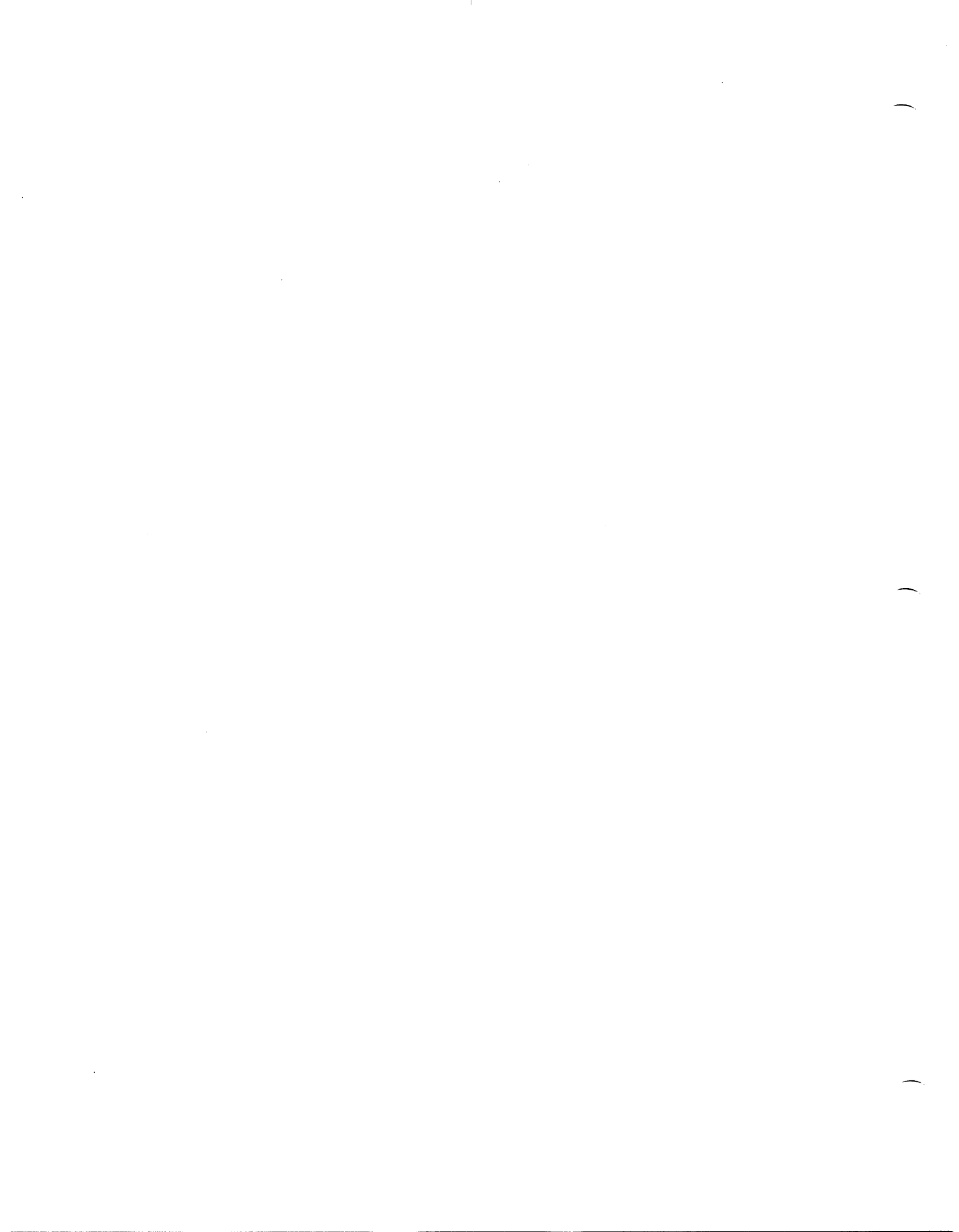
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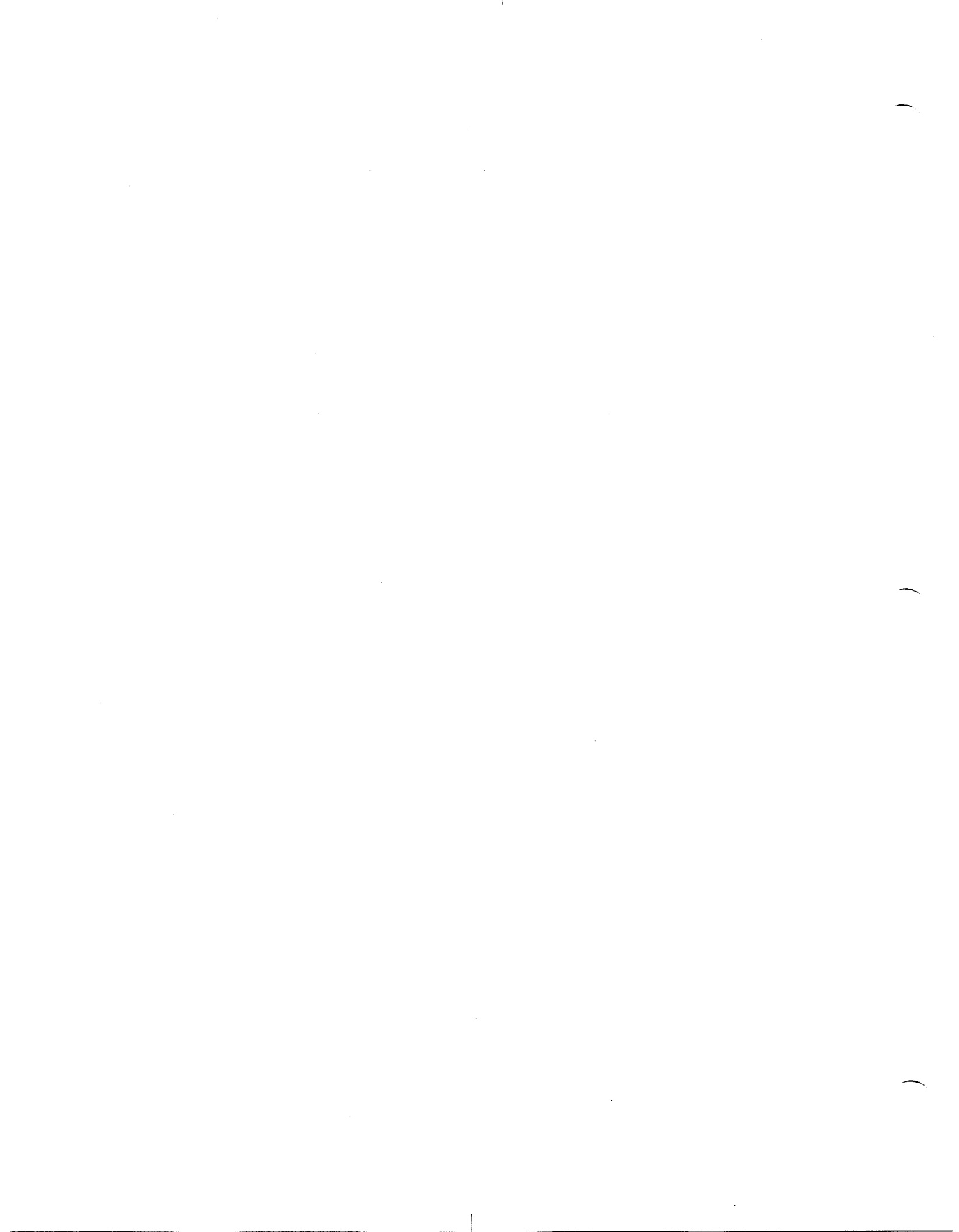
C. Environmental Impact

A categorical exclusion is claimed under 21 CFR § 25.24.



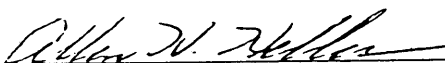
D. Economic Impact

In accordance with 21 CFR Part 10.30, an economic impact statement will be provided to FDA when requested by the Commissioner.



E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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