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**National Institute for
Health and Clinical Excellence**

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Dear

FAD for Pemetrexed Disodium for the treatment of non-small cell lung cancer

Thank you for your letter of 21 March. This letter represents my final decision on the initial validity of your appeal point brought under ground three in your letter of 1 March.

I remain unpersuaded that your ground of appeal is valid. I do not accept that there is any meaningful distinction between forming a view on clinical and cost effectiveness, and forming a view on efficacy. Efficacy and clinical effectiveness are clearly either the same or almost the same concept. If they differ, it seems to me they can differ only in that clinical effectiveness may look at real world efficacy in clinical practice, which may or may not differ from efficacy as demonstrated in trials conducted to gain regulatory approval. Not only is NICE not obliged to accept the CHMP view on clinical effectiveness, it is required to form its own view on that issue. It is not arguable that a NICE appraisal undermines the marketing authorisation for the product. Nor is it arguable that NICE was required to do more than be aware of the CHMP conclusion on efficacy, which the FAD shows it was.

Accordingly my decision is that this is not a valid ground of appeal.

Yours sincerely

Mark Taylor
Appeals Committee Chair