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I, Frank Reginald David Apps, MITI, BA Hons Cantab., of Ingatestone Translations Ltd., 3 Crown Meadow, Braintree Essex CM7 9EX, UK do hereby solemnly and sincerely declare as follows:

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(54) Title of the invention: LONG-TERM STABLE FORMULATION

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(57) Abstract

A stable G-CSF formulation having a residual ratio of G-CSF of 90% or more after long-term storage testing at 25°C for 3 months or a residual ratio of G-CSF of 90% or more after long-term storage testing at 40°C for 2 months or a residual ratio of G-CSF of 90% or more after accelerated testing at 50°C for 1 month or a residual ratio of G-CSF of 90% or more after accelerated testing at 60°C for 2 weeks and a content of Met-oxidized G-CSF of 1% or less after accelerated testing at 50°C for 1 month or after accelerated testing at 60°C for 2 weeks. A method for suppressing the formation of the methionine-oxidized variant of a physiologically active protein having methionine residues characterized by adding methionine to a composition containing this protein is disclosed.

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