

Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim: format for applications: appendices C-I

FORMAT FOR APPLICATIONS

Appendices C-I

of the

**SCIENTIFIC AND TECHNICAL GUIDANCE FOR THE PREPARATION AND
PRESENTATION OF THE APPLICATION FOR AUTHORISATION OF A HEALTH
CLAIM (Request N° EFSA-Q-2007-066)**

Page 1 of 10

Applicant:
Food/food constituent:
Place and date:

M^R DENAQUE

Pr. Maurice CLOAREC
8, Rue Duguay-Trouin
75006 PARIS - Tél. 01 42 22 29 17

Scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim: format for applications: appendices C-I

APPENDIX H – SYNOPSIS OF PERTINENT INDIVIDUAL HUMAN INTERVENTION STUDIES

Please provide one synopsis for each study.

Data below should be extracted from copies/reprints of published studies and from full study reports of unpublished studies. Since not all data below may be available in all cases, please state "not available" as appropriate.

To be included under Part 4, Section 4.2.1.1.

Comparative study of the effects of the dietary supplement 1 versus supplement of vitamin E on hyperlipoproteinemias

Pr Maurice CLOAREC – National Association of Medical Prevention, Paris – TENON Hospital Tenon, Saint Antoine University Hospital, Pierre and Marie Curie University, Paris, France

1. Identification of the study

- 1.1. Authors: Pr Maurice CLOAREC
- 1.2. Article title: Comparative study of the effects of the dietary supplement 1 versus supplement of vitamin E on hyperlipoproteinemias
- 1.3. Source (journal, conference, etc.) Year/Volume/pages/Country of origin:
- 1.4. Institutional affiliation (first author) and/or contact address: National Association of Medical Prevention, Paris - TENON Hospital, Saint Antoine University Hospital, Pierre and Marie Curie University, Paris, France
- 1.5. Declaration of interests:
- 1.6. Source of funding:
- 1.7. Good Clinical Practice status / ethical approval: approval of the saint Antoine University Hospital Institutional Review Board/ Ethics Committee

2. Report status. Please check as appropriate:

Published ☐ Accepted for publication ☐ Unpublished ☒

3. Verification of study eligibility (check if the intervention study meets inclusion criteria defined in Part 4, Section 4.1.1 on Comprehensive Review of Human Data):

4. Objective(s) of the study to compare the benefit of long-term 1 supplementation to that of vitamin E, in combination with a strict and closely followed diet in dyslipidemic patients in primary prevention

5. Description of the study population

- 5.1. Population subgroup (if not general population): dyslipidemic patients in primary prevention
- 5.2. Age range(s): 21-58 years old
- 5.3. Sex: not available
- 5.4. Ethnicity: not available
- 5.5. Inclusion criteria: hyperlipidemia with : TG > 1,50 g/l - LDLc > 1,60 g/l - HDLc < 0,50 g/l
- 5.6. Exclusion criteria: cardiovascular history/ age > 21 and < 58 years/ intercurrent medical treatment/ insulin-dependent diabetes mellitus (type 1)/ obesity according to the Framingham criteria/ hemostasis disorders
- 5.7. Setting(s):
- 5.8. Geographical region(s): Paris, FRANCE

6. Study design:

- 6.1. Design: randomised controlled trials, cross-over studies, other: randomised trial
- 6.2. Intervention arm(s): (fill boxes below as appropriate. Use N/A when not applicable)

Commentaire [u1] : A
compléter

Commentaire [u2] : A
compléter

Commentaire [u3] : A
compléter

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UNIVERSITE PIERRE et MARIE CURIE PARIS 6

Cette étude a été réalisée par des équipes formées par ce groupe :

CHU PITIE SALPETRIERE

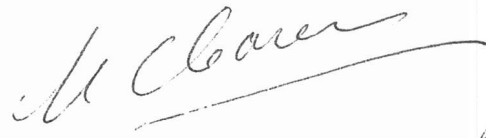
CHU SAINT ANTOINE TENON

RECRUTEMENT des volontaires :CENTRES de MEDECINE PREVENTIVE

HOPITAL AMERICAIN de NEUILLY

CENTRE INTERPROFESSIONNEL (C.I.E.M.) 15 RUE JEAN-BART 75006 PARIS

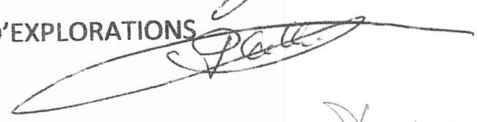
COORDINATEUR : PROFESSEUR MAURICE CLOAREC



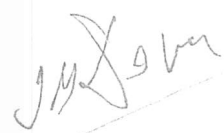
Equipes de MEDECINE PREVENTIVE : Dr YVES ELBEZE -HOPITAL AMERICAIN de NEUILLY

:Dr PHILIPPE CAILLARD CENTRE D'EXPLORATIONS

FONCTIONNELLES (1rue SAINT ANTOINE (75004)

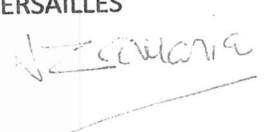


CONTROLES BIOLOGIQUES :Dr J.M.DEVER DIRECTEUR DU LABORATOIRE DU C.I.E.M



Dr N. ZAMARIA DIRECTEUR DU LABORATOIRE 49 Av de VERSAILLES

PARIS (75016)



Equipe du LABORATOIRE de L'HOPITAL AMERICAIN