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6202 AZ Maastricht

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telefax 043-387 78 78



academisch ziekenhuis  
Maastricht

**azm**

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

afdeling  
uw kenmerk  
ons kenmerk  
doorkiesnummer  
datum 9-7-01

8525 01 JUL 11 P2:32

Dear Sir,

With this letter we, the ASAS (ASsessments in Ankylosing Spondylitis) working group, would like to express our interest in taking a lead in coordinating a critical appraisal of the science related to AS in answer to your request to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders in Federal Register, vol 66, no 98, May 21, 2001, notices.

The ASAS working group comprises epidemiologists, rheumatologists, and representatives of patient groups and industry with a special interest in the research of AS and related disorders. Many of them are opinion leaders in this field. The ASAS working group represents more than 20 countries. ASAS has started in 1995, organises regular meetings and workshops (at least twice a year), and conducts research, mainly in the field of outcome assessment in AS. As a result of these efforts core sets for the assessment of disease activity and outcome in various situations have been developed. In addition to this, response criteria based on a statistical data-driven approach have been proposed. At the moment, these response criteria are being tested against the "expert judgement" making use of a Delphi exercise. Publications in relation to the research performed, as well as a summary of the ongoing research agenda is attached to this letter. We would like to mention that Jennifer Anderson, Boston, has been deeply involved in the development of the ASAS set of responder criteria and that she could be of great value in participating at this process.

Taking into account the members of the ASAS working group and the scope of the research performed by this group, we would be happy to collaborate in the development of a guidance document including the critical appraisal that is needed for that purpose. We also would like to participate in a public meeting permitting to discuss selected relevant questions.

OID-0193

CS

academisch ziekenhuis  
Maastricht

pagina  
ons kenmerk  
datum

On behalf of all ASAS working group members (a list of the members is enclosed),

The steering committee,

Prof. N. Bellamy, Brisbane, Australia

Dr. A. Calin, Bath, UK

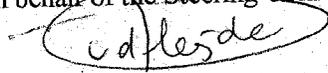
Prof. M. Dougados, Paris, France

Prof. D. van der Heijde, Maastricht, the Netherlands

Prof. A. Khan, Cleveland, USA

Prof. Sj. van der Linden, Maastricht, the Netherlands

On behalf of the Steering Committee,



Prof. D. van der Heijde  
Department of Internal Medicine  
Division of Rheumatology  
University Hospital Maastricht  
PO Box 5800  
6202 AZ Maastricht  
The Netherlands

### Publications by ASAS

1. Spoorenberg A, van der Heijde D, de Klerk E, Dougados M, de Vlam K, Mielants H, et al. A comparative study of the usefulness of the Bath Ankylosing Spondylitis Functional Index and the Dougados Functional Index in the assessment of ankylosing spondylitis. *J Rheumatol* 1999;26:961-5.
2. Spoorenberg A, van der Heijde D, de Klerk E, Dougados M, de Vlam K, Mielants H, et al. Relative value of erythrocyte sedimentation rate and C-reactive protein in assessment of disease activity in ankylosing spondylitis. *J Rheumatol* 1999;26:980-4.
3. Spoorenberg A, de Vlam K, van der Heijde D, de Klerk E, Dougados M, Mielants H, et al. Radiological scoring methods in ankylosing spondylitis: reliability and sensitivity to change over one year. *J Rheumatol* 1999;26:997-1002.
4. van der Heijde D, Calin A, Dougados M, Khan MA, van der Linden S, Bellamy N. Selection of instruments in the core set for DC-ART, SMARD, physical therapy, and clinical record keeping in ankylosing spondylitis. Progress report of the ASAS Working Group. Assessments in Ankylosing Spondylitis. *J Rheumatol* 1999;26:951-4.
5. van der Heijde D, van der Linden S, Bellamy N, Calin A, Dougados M, Khan MA. Which domains should be included in a core set for endpoints in ankylosing spondylitis? Introduction to the ankylosing spondylitis module of OMERACT IV. *J Rheumatol* 1999;26:945-7.
6. van der Heijde D, van der Linden S, Dougados M, Bellamy N, Russell AS, Edmonds J. Ankylosing spondylitis: plenary discussion and results of voting on selection of domains and some specific instruments. *J Rheumatol* 1999;26:1003-5.
7. Ruof J, Stucki G. Comparison of the Dougados Functional Index and the Bath Ankylosing Spondylitis Functional Index. A literature review. *J Rheumatol* 1999;26:955-60.
8. Ruof J, Sangha O, Stucki G. Comparative responsiveness of 3 functional indices in ankylosing spondylitis. *J Rheumatol* 1999;26:1959-63.
9. Ruof J, Stucki G. Validity aspects of erythrocyte sedimentation rate and C-reactive protein in ankylosing spondylitis: a literature review. *J Rheumatol* 1999;26:966-70.
10. van der Heijde D, van der Linden S, Bellamy N, Calin A, Dougados M, Khan MA. Which domains should be included in a core set for endpoints in ankylosing spondylitis? Introduction to the ankylosing spondylitis module of OMERACT IV. *J Rheumatol* 1999;26:945-7.
11. Anderson JJ, Baron G, van der Heijde D, Felson DT, Dougados M. Ankylosing Spondylitis ASsessment group preliminary definition of short-term improvement in ankylosing spondylitis. *Arthritis Rheumatism* (in press)
12. Auleley G, Benbouazza K, Collantes E, Hajjaj-Hassouni N, van der Heijde D, Spoorenberg A, Dougados M. Evaluation of the smallest detectable difference in symptomatic outcome variables in ankylosing spondylitis. (submitted)

## Research agenda ASAS

- Delphi exercise to compare expert judgments with ASAS preliminary response criteria
- Performance of response criteria in trials with biological agents
- Additional value of CRP above ESR
- Severity of morning stiffness of the spine compared to duration of morning stiffness
- Various scoring methods of X-rays
- MRI of the spine as an outcome measure for disease activity and severity
- BASDAI
- BASMI
- Co-calibration of BASFI and Dougados FI
- Validation of QoL instruments in AS

## ASAS list June 25, 2001

Name	Residence	Country
Prof. A.O. Adebajo	Barnsley	United Kingdom
Dr. B.L. van Albada	Oranjewoud	The Netherlands
Prof. B. Amor	Paris	France
Prof. J. Barlow		United Kingdom
Prof. N. Bellamy	Brisbane	Australia
Prof. L. Benevolenskaya	Moscow	Russia
Prof. H. Bird	Leeds	United Kingdom
Prof. M. Boers	Amsterdam	The Netherlands
Dr. A. Boonen	Maastricht	The Netherlands
Prof. J. Braun	Herne	Germany
Prof. P. Brooks	Brisbane Herston	Australia
Mrs. J. Bruckel	Serman Oaks	United States of America
Dr. R. Burgos Vargas	Mexico city	Mexico
Dr. A. Calin	Bath	United Kingdom
Prof. D. Clegg	Salt Lake City	United States of America
Dr. E. Collantes Estevez	Cordoba	Spain
Dr. J. Darmawan	Semarang	Indonesia
Dr. J. Davis	San Francisco	United States of America
Dr. P. Dawes	Staffordshire	United Kingdom
Dr. A.J. Dekker-Saeys	Aerdenhout	The Netherlands
Prof. M. Dougados	Paris	France
Prof. B.A.C. Dijkmans	Amsterdam	The Netherlands
Prof. A. Ebringer	London	United Kingdom
Prof. J. Edmonds	Sydney	Australia
Dr. N. Feltelius	Uppsala	Sweden
Dr. M. Ferraz	Sao Paolo	Brasil
Dr. P. Géher	Budapest	Hungary
Prof. J.T. Gran	Tromso	Norway
Dr. F. Guillemin	Vandoevre les Nancy Cedex	France
Prof. D. van der Heijde	Maastricht	The Netherlands
Dr. I. van der Horst-Bruinsma	Amsterdam	The Netherlands
Dr. R. Juhlin	Rotebergsvägen	Sweden
Prof. M.A. Khan	Cleveland	United States of America
Dr. J. Kirazli	Izmir	Turkey
Dr. F. Klareskog	Stockholm	Sweden
Prof. T. Kvien	Oslo	Norway
Prof. M. Leirisalo-Repo	Helsinki	Finland
Prof. Sj. van der Linden	Maastricht	The Netherlands
Dr. A. Linssen	Ijmuiden	The Netherlands
Prof. B.A. Michel	Zürich	The Netherlands
Prof. H. Mielants	Bent	Belgium
Prof. I. Olivieri	Potenza	Italy
Dr. G. van Overeem Hansen		Denmark
Dr. P. Peloso	Saskatoon	Canada
Dr. C. Ramos-Remus	Colomos	Mexico
Prof. P. van Riel	Nijmegen	The Netherlands
Mr. F. Rogers	Mayfield	United Kingdom
Prof. A.S. Russell	Edmonton	Canada
Dr. C. Salvarani	Bologna	Italy
Prof. J. Sieper	Berlin	Germany
Dr. E. Stanislawska-Biernat	Warszawas	Poland
Prof. G. Stucki	Munchen	Germany
Prof. R. Sturrock	Glasgow	United Kingdom
Dr. G.T.D. Thomson	Winnipeg	Canada
Prof. P. Tugwell	Ottawa	Canada
Prof. E. Veys	Gent	Belgium
Dr. D.E. Yocum	Tuscon	United States of America
Prof. H. Zeidler	Hannover	Germany

**INSTYTUT REUMATOLOGICZNY**

02-637 Warszawa, ul. Spartańska 1  
tel. centr. 44-42-41, tel/fax 44-95-22, 44-77-97

8526 01 JUL 11 P2:32

Znak .....

Data .....

Warsaw, 03.07.2001.

Ewa Stanisławska-Biernat MD, PhD  
Prof. ass.  
Rheumatology Clinic  
Institute of Rheumatology  
02-637 Warsaw  
Poland

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,

Ewa Stanisławska-Biernat

8527 '01 JUL 11 P2:32

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,

*A. BOONEN*

A handwritten signature in black ink, appearing to read "A. Boonen". The signature is written in a cursive style with a long, sweeping underline that extends to the right.

**CIADS** CENTRE FOR INFLAMMATORY AND ARTHRITIC DISEASE STUDIES

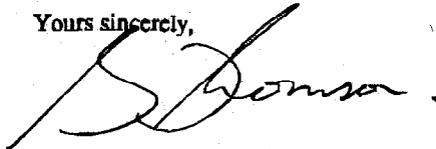
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857  
9-7-01  
 ADVANCE

8528 '01 JUL 11 P2:32

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,



706-233 KENNEDY STREET / WINNIPEG, MB CANADA R3C 3J5 / PHONE (204) 947-1766 / FACSIMILE (204) 947-1804

8529 '01 JUL 11 P2:32

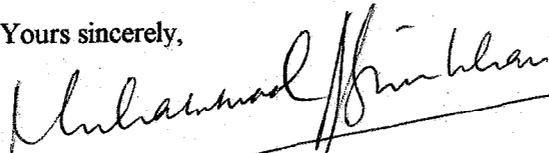
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

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Yours sincerely,



Muhammad A. Khan, MD

Professor of Medicine

Case Western Reserve University,

MetroHealth Medical Center, Division of Rheumatology

2500 MetroHealth Drive

Cleveland, OH 44109

USA

KENNEMER GASTHUIS

8530 '01 JUL 11 P2:32

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

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Yours sincerely,



dr. A. Linssen  
reumatoloog

dr. A. Linssen  
reumatoloog

**LÄKEMEDELSVERKET**  
MEDICAL PRODUCTS AGENCY

Division of Clinical Trials  
N Feltelius/mm

Date  
27 June, 2001

Dnr  
159:88/01

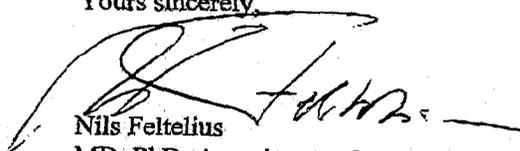
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
ROCKVILLE, MD 20857  
USA

8531 01 JUL 11 P2:33

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,



Nils Feltelius  
MD, PhD, Associate professor in Rheumatology  
Department of Medicine, Karolinska Institute and  
Division of Clinical Trials  
Medical Products Agency  
S-751 03 Uppsala  
Sweden

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WHO Collaborating Center  
Community-based Epidemiology, Prevention,  
and Treatment of Rheumatic Disease,  
Seroja Rheumatic Center (SRC)



John Darmawan, MD, PhD, FACR: Director

Member, WHO Expert Committee on Rheumatic Disease, Geneva, Switzerland

Medicare – Consultations, Jalan Seroja Dalam 7, Semarang 50136

Tel: 62 24 8316 496, 62 24 8447 345, Fax 62 24 8310 028

Email: jd131035@hotmail.com

July 23, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,

John Darmawan, MD, PhD  
Director, Seroja Rheumatic Center



THE NATIONAL ANKYLOSING SPONDYLITIS SOCIETY

NASS Reg. Charity No. 272258

PO BOX 179 • MAYFIELD • EAST SUSSEX • TN20 6ZL

Tel: 01435 873527

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Website: [www.nass.co.uk](http://www.nass.co.uk) • e-mail: [nass@nass.co.uk](mailto:nass@nass.co.uk)

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

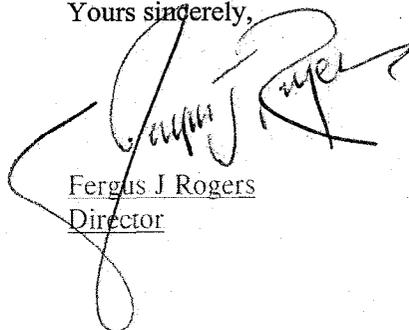
9-7-01

8533 01 JUL 11 P2:33

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,



Fergus J Rogers  
Director

Vice President:  
Dr. A. St. J. Dixon, M.D., F.R.C.P.

Chairman:  
Dr. A. Calin, M.D., F.R.C.P.

Treasurer:  
Mr. E.N.C. Eustance, F.C.M.A., M.C.T.

Director:  
Mr. F.J.R.S. Rogers

**SPONDYLITIS**  
ASSOCIATION OF AMERICA

AS

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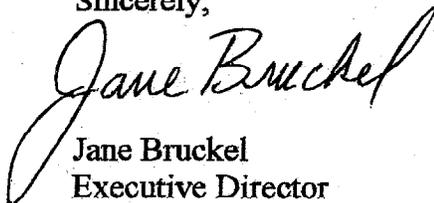
June 29, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20857

Dear Sir,

As a member of the ASAS working group, I would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Sincerely,



Jane Bruckel  
Executive Director

Fax 043-3875006

8535 '01 JUL 11 P2:33

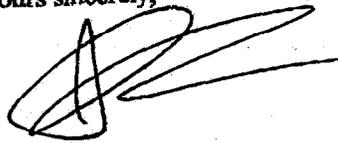
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,



I.E. van der Horst-Bruinsma, MD, PhD  
Department of Rheumatology  
Vrije Universiteit Medical Centre  
PO Box 7057  
1007 MB Amsterdam  
The Netherlands

8536 '01 JUL 11 P2:33

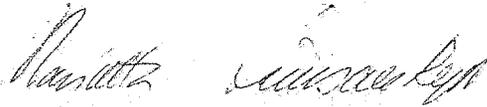
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

Dear Sir,

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Yours sincerely,



Marjatta Leirisalo-Repo, MD  
Professor of Rheumatology  
Helsinki University Central Hospital  
Department of Medicine  
Division of Rheumatology  
PO BOX 263  
FIN-00029 HUS  
Finland

# Royal National Hospital for Rheumatic Diseases

NHS Trust

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Bath, BA1 1RL

Telephone: 01225 465941

AC/EFA/

Tel (direct) 01225-473442  
Fax(direct) 01225-473437  
From USA 011 44-1225 465941  
Email: [andrei.calin@virgin.net](mailto:andrei.calin@virgin.net)

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane rm 1061  
Rockville  
MD 20857  
USA

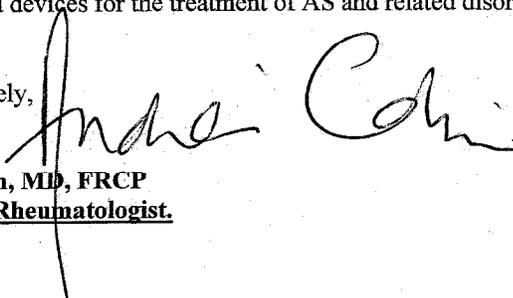
26<sup>th</sup> June 2001

053701  
JUL 11 P2:34

Dear Sir

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,



**Andrei Calin, MD, FRCP**  
**Consultant Rheumatologist.**



INVESTOR IN PEOPLE





UNIVERSITY OF ALBERTA 8538 01 ALBERTA 2:34

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BSc, MD, FRCP (C)  
407-6762  
E-mail: stephen.aaron@ualberta.ca

*Paul Davis*  
MB, CHB, FRCP (C) FRCP (UK)  
407-5294  
E-mail: paul.davis@ualberta.ca

*Joanne E. Homik*  
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407-8070  
E-mail: jhomik@gpu.srv.ualberta.ca

*Walter P. Maksymowych*  
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*Anthony S. Russell*  
MA, MB, BChir, FRCP (C), FRCP  
407-5296  
E-mail: asr@gpu.srv.ualberta.ca

June 25, 2001

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857  
USA

Dear Sir:

As a member of the ASAS working group, I would like to express my support of the initiative of this group in taking a lead in coordinating a critical appraisal of the science related to ankylosing spondylitis. This initiative specifically refers to the request of the FDA to assist in the development of guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,

A handwritten signature in black ink, appearing to read "A.S. Russell".

A.S. Russell, F.R.C.P.(C)

ASR/js

Department of Medicine  
Division of Rheumatology/Clinical Immunology

562 Herirage Medical Research Centre • University of Alberta • Edmonton • Canada • T6G 2S2

Fax (780) 407-6055

\* denotes Professional Corporation



# MEDIZINISCHE HOCHSCHULE HANNOVER

## Abteilung Rheumatologie

Prof. Dr. H. Zeidler

Zentrum Innere Medizin und Dermatologie

8539 01 JUL 11 P2:34

MHH - Rheumatologie - 30623 Hannover

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

Telefon Hannover (05 11)

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Rheumatol. Station 51 5 32 - 23 11 / 23 12

Rheumatologische Ambulanz 5 32 - 62 86  
Studien-Ambulanz 5 32 - 52 52

Rheumatol. Labor 5 32 - 38 16

interdisziplinäre orthopädisch-  
interne Rheumatologie  
im Annusstift 53 54 - 1 04  
Leiter Prof. Dr. C.J. Wehn  
1. Stellv. Prof. Dr. H. Zeidler

Telefax 5 32 - 58 41

Unser Zeichen

Prof. Zei/Kö-St

Durchwahl-Nr.

(05 11) 5 32 -

2190

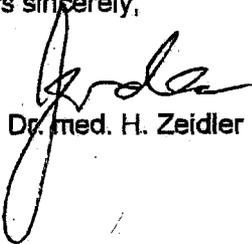
Hannover

2001-06-26

Dear Sir,

with this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely,

  
Prof. Dr. med. H. Zeidler

zei-ASAS/a:83

Dienstgebäude

Konstanty-Gutschow-Str. 8

Telefon (05 11) 5 32 - 1

Telefax 9 22 044

Kontoverbindungen

Konto-Nr. 370 371

Stadtparkasse Hannover (BLZ 250 501 00)

GESAMT SEITEN 02

26/06 '01 DIN 14:05 [TX/RX NR 5850] 002

РОССИЙСКАЯ АКАДЕМИЯ МЕДИЦИНСКИХ НАУК  
ИНСТИТУТ РЕВМАТОЛОГИИ

№ \_\_\_\_\_  
на № \_\_\_\_\_ от \_\_\_\_\_

115522, г. Москва, Каширское ш., д. 34-а.  
Телефон: 114-44-90, 114-44-41, 114-39-65  
Факс: 114-44-68

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

9-7-01

Dear Sir,

With this letter I, being a member of the ASAS working group, would like to express my support to the initiative of the ASAS working group in taking a lead in coordinating a critical appraisal of the science related to AS. This initiative refers to the request of the FDA to assist in the development of a guidance for industry on issues related to drugs, biological products, and devices for the treatment of AS and related disorders.

Yours sincerely, 

Dr. Shandor Erdesz, MD, PhD,  
Scientific Director  
Institute of Rheumatology  
Kashirskoye Shosse 34A  
115522, Moscow, Russia  
Tel/Fax: +7(095) 114-4486

8541 '01 JUL 11 P2:34

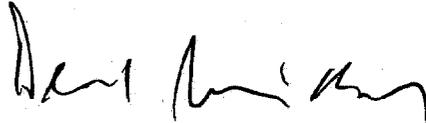
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville  
MD 20857

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Yours sincerely,



UniversitätsSpital Zürich  
Prof. Dr. med. B. A. Michel  
Direktor Rheumaklinik  
Gloriastrasse 25  
CH-8091 Zürich

OFFICE OF THE EXECUTIVE DEAN (HEALTH SCIENCES)

EXECUTIVE DEAN (HEALTH SCIENCES)  
**PROFESSOR PETER BROOKS**  
MD, FRACP, FAIRM, FAFPHM



**THE UNIVERSITY OF QUEENSLAND**

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
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8542

9.7.01

JUL 11 P2 34

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Yours sincerely,

# FedEX International Air Waybill

Origin Copy

FedEx Tracking Number **8260 7240 2483** Form I.D. No. **0408**

PACKAGE LABEL COMMERCIAL INVOICE LABEL DELIVERY RECORD LABEL DELIVERY BEAT/TEMP LABEL

826072402483

826072402483

826072402483

**1 From**

Date 07/09/2001 Sender's FedEx Account Number 1015-5528-2

Sender's Name INT. CRME Phone 0433875571

Company ACADEMISCH ZIEKENHUIS

Address DEE CREDITEURENADMINISTRATIE

P. DERVELAAN 25

MAASTRICHT NL Postal Code 6220

**2 Your Internal Billing Reference**

**3 To**

Recipient's Name Dockets Management Branch Phone \_\_\_\_\_

Company (HEA-305) Food and Drug Administration

Address Law 5630 Fishers Lane #11061

City Bockville State/Province \_\_\_\_\_

Country USA ZIP Postal Code MD 20057

Recipient's Tax I.D. number for Customs purposes \_\_\_\_\_  
e.g., INVA/EN, or as locally required

**4 Shipment Information** ALL shipments can be subject to Customs charges.

Total Packages 1 Total Weight 0.85 kg DIM L I W I H cm

Commodity Description	Harmonized Code	Country of Manufacture	Value for Customs
<u>Documents</u>			

Total Declared Value for Carriage \_\_\_\_\_ Specify Currency \_\_\_\_\_ Total Value for Customs NV

For EU only. Tick here if goods are not in free circulation and provide CI.

**5 Express Package Service** Packages up to 68 kg. For packages over 68 kg, use the FedEx Expanded Service Int. Air Waybill. **Not all services and options are available to all destinations.**

FedEx Intl. Priority  FedEx Intl. First Available to select locations. Higher rates apply.

**6 Packaging** These unique brown boxes with special pricing are provided by FedEx for FedEx Intl. Priority only.

FedEx Envelope  FedEx Pak  Other Pkg. Includes FedEx Box, FedEx Tube, and Custom net pkg.

PW  FedEx 10kg Box  FedEx 25kg Box

**7 Special Handling**

HOLD at FedEx Location  SATURDAY Delivery Available to select locations.

**Shipper must tick:**  
 This shipment does not contain Dangerous Goods. Dangerous Goods cannot be shipped using this Air Waybill.

**8a Payment Bill transportation charges to:**

Sender Acct. No. in Section 1 will be billed.  Enter FedEx Acct. No. or Credit Card No. below.

Recipient  Third Party  Credit Card  Cash Cheque

FedEx Acct. No. \_\_\_\_\_ Credit Card No. \_\_\_\_\_  
Exp. Date \_\_\_\_\_ Obtain Recip. Acct. No. \_\_\_\_\_

**8b Payment Bill duties and taxes to:** FedEx cannot estimate Customs charges.

Sender Acct. No. in Section 1 will be billed.  Enter FedEx Acct. No. below.

Recipient  Third Party  Cash Cheque

FedEx Acct. No. \_\_\_\_\_

**9 Required Signature**

Use of this Air Waybill constitutes your agreement to the Conditions of Contract on the back of this Air Waybill. Certain international treaties, including the Warsaw Convention, may apply to this shipment and limit our liability for damage, loss, or delay, as described in the Conditions of Contract.

Sender's Signature: \_\_\_\_\_ Date Executed: 07/09/2001

This is not authorization to deliver this shipment without a recipient signature.

Received above shipment in good order and condition. We agree to pay all charges including Customs duties and taxes as applicable and to the Conditions of Contract as stated on the reverse side of the Recipient's Copy.

Recipient's Signature: \_\_\_\_\_

FedEx Tracking Number **8260 7240 2483 0408**

Origin Station I.D. EINA Destination Station I.D. GAIA URSA Routing EMGAIA

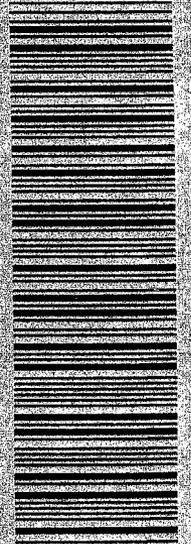
Handling Units 345 Total Volume (cm) \_\_\_\_\_

Received At  Reg. Stop  Air-Call Stop  Drop Box  World Service Center  Station

Forms Attached:  CI  RED  GD

Base Charge  Declared Val. Chrg.  Other ODA/OPA  Credit Card Auth.

FedEx Emp. # 62930 Audit Emp. # \_\_\_\_\_ Date 7/9/01 Time \_\_\_\_\_ Del. Counter Emp. # \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_



**345**

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Form I.D. No.